April 2013

MAN 1201 A THORACENTESIS SURGICAL SIMULATOR FOR MEDICAL TRAINING

Brian Arthur Schopka
Worcester Polytechnic Institute

Caitlin Marie Zuschlag
Worcester Polytechnic Institute

Shashank Shukla
Worcester Polytechnic Institute

Project Number: MAN-1201

A THORACENTESIS SURGICAL SIMULATOR FOR MEDICAL TRAINING

A Major Qualifying Project Report:

Submitted to the Faculty

Of the

WORCESTER POLYTECHNIC INSTITUTE

In partial fulfillment of the requirements for the

Degree of Bachelor of Science

by

Brian Schopka

____

Shashank Shukla

____

Caitlin Zuschlag

____

Date: April 23, 2013

1. Thoracentesis
2. Surgical Simulator
3. Fluid Drainage

Approved:

Prof. Mark Norige, Advisor

____

Debra Heitmann M.D., co-advisor

____

Melinda Taylor, co-advisor

____

Table of Contents

Table of Figures

Table of Tables

Authorship

Abstract	Shashank Shukla
Introduction	Shashank Shukla
Literature Review	Shashank Shukla
Project Strategy	All, Brian Schopka (Edits)
Alternative Designs	All, Brian Schopka (Edits)
Design Verification	Caitlin Zuschlag
Discussion	Shashank Shukla
Final Design and Validation	Caitlin Zuschlag
Conclusions and Recommendations	Brian Schopka

Acknowledgements

The team would like to thank WPI and University of Massachusetts Medical School for providing the facilities necessary to complete the project. The team would also like to thank WPI advisor Prof. Mark Norige for his constant support and advice in the engineering approach to the project. Furthermore, the project would not have been possible without key medical and surgical insight from Dr. Debra Heitmann, attending physician in the Department of Emergency Medicine at University of Massachusetts Medical School. Finally, Melinda Taylor, Sr. Engineering at the Center for Experiential Learning and Simulation provided tremendous guidance and aid towards completion of the project.

Abstract

Thoracentesis is a surgical procedure involving the drainage of fluid from the pleural space for therapeutic or diagnostic purposes such as relieving pain and verifying the presence of cancer, pneumonia or other diseases. Over the years, engineers and emergency surgeons have expressed a need for physiologically accurate surgical models on which medical professionals can train. This paper describes the design of a new model to provide hands-on practice of the Thoracentesis procedure. It uses various readily available materials to mimic the different parts of the thoracic cavity, such as, ribs, lungs, tissue layers, and a fluid containing pleural space. This model contains replaceable parts and allows the medical professionals to routinely and repeatedly practice each step of the procedure. The values of penetration force testing and other mechanical testing were within range of human tissue, verifying the similarities. Thoracentesis performed by a surgeon on the model further confirmed the physiological and surgical accuracy. We conclude that the surgical model will be able to provide accurate training for the procedure, while minimizing the cost to manufacture.

Introduction

Medical procedures are a crucial part of treating a patient to relieve pain or for diagnosing a specific disease. Specifically, emergency medical procedures are required when there is an immediate need to relieve pain or prevent patient death. In 2009, about 136.1 million visits to hospital emergency departments occurred, and about 48.0 million surgeries were performed in the United States.[1] Without emergency medical procedures, a patient could become worse or suffer more traumatic injuries and consequences. Therefore, it is important for medical professionals, including surgeons, emergency doctors, and medical students to be proficient in such procedures. In order to save a patient's life often there is little time to act and doctors must be prepared to act efficiently and to reduce chances of making a mistake. An estimated five to ten surgical procedures are performed incorrectly in the US on a daily basis.[2] To prevent such mishaps, surgeons must be ready and properly trained to act correctly to avoid errors.

One cause for a visit to the emergency department is when fluid accumulates in the cavity between the lungs and the ribs. This occurs annually in about 1.5 million people in the United States.[1] Fluid buildups and accumulation occurs especially if the patient is suffering from cancer, pneumonia, or congestive heart failure. As is the case with many emergency procedures, draining fluid from the chest is an invasive procedure, which requires specific skills. The procedure to drain the fluid from the cavity containing the lungs is known as Thoracentesis. It is a medical emergency procedure that requires a high degree of skill and knowledge to perform successfully. All emergency medical procedures do not require such high skill and knowledge and are routinely performed by EMT's and other emergency medical personnel, such as giving someone oxygen, first aid or CPR. A surgeon is provided with a detailed list of steps that outline the procedure, however, without sufficient training, it could be more harmful than helpful. Doctors must undergo rigorous training for procedures such as Thoracentesis, in order to perfect the technique and eliminate any errors that may occur while performing this procedure on a patient in an emergency.

Surgical models have been used for such training purposes for years, and they have gone through major changes in the past. They range from using a cadaver or an animal model, to using synthetic physical models, and even computer generated virtual reality models. Although cadavers and animal models are more realistic for human training purposes, they may differ in physiology, are limited in simulating desired symptoms and with animals carry ethical concerns from humane societies. Virtual reality models in development do not provide the exact physical practice the surgeons need. Lastly, the most commonly used artificial models are the synthetic models created with materials to mimic the properties of human tissues.

Specifically, two major producers of synthetic models are TraumaMan® and SynDaver Labs™. They both create anatomically accurate models to allow medical professionals to practice surgery; however, they are expensive (range of $5,000 to$25,000 each) and therefore can be unaffordable by many medical practices. Furthermore, they also are limited for use for Thoracentesis training as they lack fluid containing components, especially in TraumaMan®. Therefore, until now, there is no good synthetic anatomically accurate surgical training available for Thoracentesis procedures. The overall goal of this project is to create such a model and provide the essential replaceable components needed to repeatedly practice the procedure, while minimizing the manufacturing cost.

By utilizing commonly found materials that mimic the properties of the various tissues such as ribs, skin, muscle, fat, and lungs, we wish to create a model that will accomplish the given task. Additionally, through the help of our advisors, we also hope to provide the user with physiological and procedural accuracy. In order to provide a better understanding of the model, it is necessary to talk about the procedure itself and the anatomy of the thoracic cavity. Additionally, there are several alternative designs our team considered, however, through testing we decided on a best design. We also need to verify the accuracy and efficiency of the model through mechanical testing and compare it to literature values on the human tissue. Based on such data, we ask a surgeon to perform the procedure itself and verify the accuracy of the training model. As there are several anatomically accurate models on the market, they are either too expensive or not suitable for use with the Thoracentesis procedure. Therefore, through our model we plan to provide surgeons with a better device for Thoracentesis training at a lower cost.

Literature Review

Introduction

Emergency medicine holds true importance in the field of healthcare and is critical in saving patients lives. The several trauma and therapeutic procedures performed under such care have become crucial in developing a safer treatment system.

Nevertheless, the field of emergency medicine requires that certain actions must be performed quickly to prevent disability or death of a patient. Since 2008, approximately $47 billion has been spent towards emergency medicine out of the $3 trillion spent on all healthcare.[3] However, some procedures performed are part of both emergency and non-emergency situations depending on the individual diagnosis. About 48 million inpatient medical procedures, ranging from Computer Aided Tomography (CAT Scan) to cardiac catheterization, are performed each year.[4] In order to perfect these procedures, during training, medical students and professionals make use of surgical simulators and cadavers.

Ethical Issues

Performing an emergency surgical procedure like Thoracentesis, which is the focus of this project, requires practice to develop proficiency. Presently, surgeons learn Thoracentesis by practicing on simulators, cadavers, and even animal subjects. Although simulators are ideal for "low-frequency but high-acuity" procedures that require the use of a specialist, emergency physicians need to know how to perform such procedures in time of urgency.[5] Therefore, the surgical simulators allow physicians not trained in the specific field to practice to perform such specific procedures with repeatability. With the aforementioned methods for practice, there are several disadvantages in educating the physician and ethical dilemmas.

Every year, about 20 million animals are killed due to experimentation, and out of those, about eight million are used in painful experiments.[6] Although, advocates state that animal testing is crucial to scientific progress, the technology in 2013 should allow for safer alternatives to experiment and practice surgery. If animals are thought to have the inability to reason and talk, how come artificial surgical simulators are not used more often? At least they do not have the ability to suffer.[6] Many complaints have also been filed for the use of dogs used in the practice of trauma procedures[7] and there are better ways to teach physicians the same skills. Animals are being collected and euthanized just for surgical practice and although they replicate the biological experience of live tissue, it is unethical on various levels. The humane society disagrees with the practice and The University of Michigan has condoned such controversial practices.[7] It is easier to use a surgical simulator, which can offer repetitive practice without harming a live being. It can also be reused and recycled as opposed to the animal models that are sacrificed. As a result, surgical simulators are safer and more ethical alternatives to using animals for practicing procedures.

Necessity

Surgical simulators also hold true importance because they allow the surgeon to practice at their own pace repeating the practice until they are proficient. Similar to airline pilots using flight simulators, the surgical simulators allow physicians to maintain their skills.[5] One study of the use of surgical simulators in training showed that simulated surgical evaluations were able to assess and discriminate the skillset of 120 physicians on various levels.[8] This allows the physician to be evaluated on the cognitive and procedural levels and allow them to practice on specific parts that may require further practice. As is the focus of this project, thoracic surgical skills are also very important and the effectiveness of high fidelity, low-cost simulators has aided surgical training for skill development.[9] Marshall and Carter conducted a study with replicas of human torso, where student volunteers performed a lobectomy. Objective data demonstrated a success rate of 88.9% with significant improvements with weekly repetition.[9] The increased rate in success demonstrated that surgical simulators are indeed very helpful in aiding the medical student with the procedure. Furthermore, the study also showed that through repetition, the operative time was reduced by about 14 minutes[9] concluding that the simulator can be an effective tool in teaching thoracic surgery techniques. The simulator allows the evaluation of the physician's competencies as well.[8] Simulators permit learners to work at their own pace without having the concern of time and distractions as in an operating room.

Although it is beneficial for a physician to get the “real-time” experience, it is unadvisable to operate on a live human being without prior training.[5] Practicing on a simulator allows for repetition and that is the best way to hone one’s skillset. Pamela Andreatta, the director of the Clinical Simulator Center at University of Michigan explains that surgical simulators allow the physician to assess their standard skills because patient outcomes are unique to the patient and are unable to tell the true story about the skillset.[10] She argues that physicians can encounter the same problem and task and receive immediate feedback.[5] It has been argued that surgical simulators are unable to provide the *feel* that is provided by the cadavers or the animal models. They have also been criticized for their lack of accuracy; however, they are a much safer training method approved by the humane societies. With proper tools and budget, the simulators can come very close to the human model in terms of anatomy and physiology. Cadavers are limited and use of animal models for training may be unethical and wasteful. Hence, surgical simulators allow standardization of training, safe and repetitive practice, rehearse treatment, and allow educators to set standards for performance and skills.

Nevertheless, before designing a new simulator, an understanding of human anatomy and material properties of related tissues of the human torso is required. Since the Thoracentesis model focuses on the pleural cavity, the anatomical aspect of the surgery and the steps required to perform the surgery must be reviewed.

Anatomy of a Human Torso

The human thoracic cavity houses most of the internal organs of the cardiovascular, digestive, and the respiratory systems. It also contains and protects the heart, lungs, trachea, esophagus, diaphragm, and major nerves and blood vessels.[11] This project focuses on the procedures performed on the pleural cavity part of the anatomy. The pleural cavity encapsulates the lungs and the heart and the pleura is known as the monolayer of mesothelial cells that cover the lung and the inner surface of the chest cavity.[12] The pleura covering the lung is known as the visceral pleura and the one covering the costal wall is known as the parietal pleura.[11] The space between the two pleura is known as the pleural space and has been the location of several health problems that result in fluid accumulation in the pleural space. This space is approximately 10 to 20 μm wide and stomata within the pleural wall allow for normal diffusion of fluid.[13] There are several layers to the cavity between the skin and the visceral pleura that protect and encase the lungs.

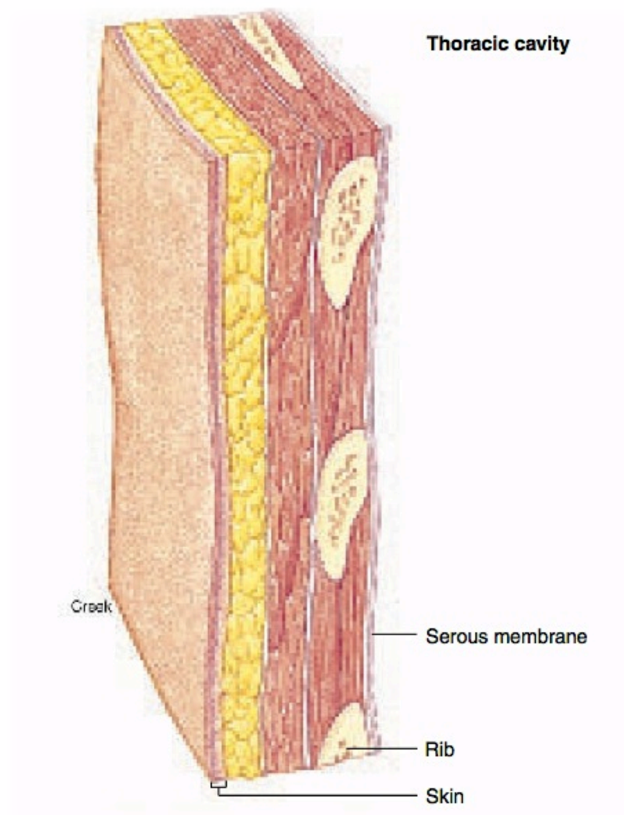


Figure 1: Layers from the skin to the parietal pleura[11]

As it can be seen from Figure 1, there are several layers of fat and muscle between the ribs and the skin. The ribs are also part of the cavity and play an important role in the structural integrity of the torso while also providing protection to the internal organs.

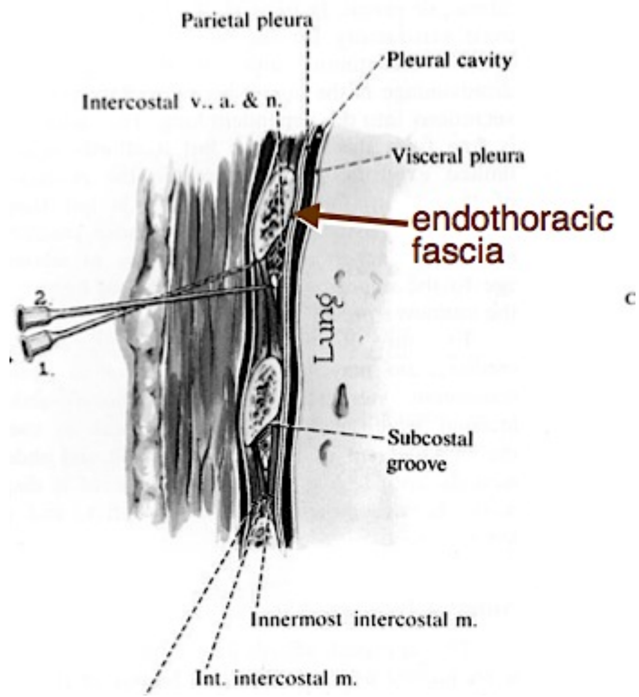


Figure 2: Portrayal of the pleural cavity and the lungs[11]

Figure 2 also illustrates the layers with labels that describe the pleural space. Although the pleural space seems like a very thin layer of space, serious issue arise if fluid accumulates into the space, through trauma or from disease. Thus is the focus of this project, which is to evaluate the steps in a procedure known as Thoracentesis and create an anatomically accurate surgical simulator for the medical professionals to practice such procedure.

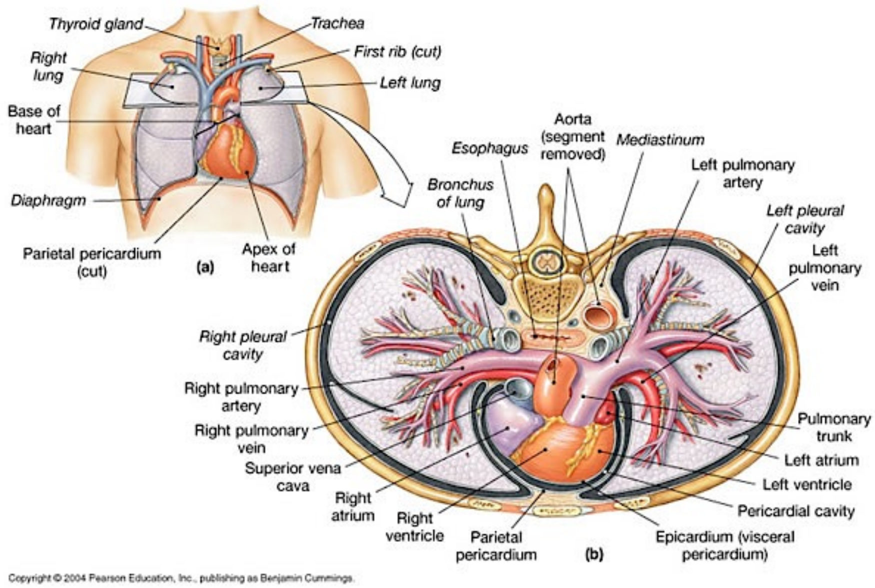


Figure 3: Transverse view of the thoracic cavity[14]

Figure 3 is a representation of the transverse view of the thoracic cavity. The left and the right lungs are completely separated by the pleura and are encased within the rib cage. Additionally, the heart, esophagus, trachea, and the major blood vessels are contained in the middle of the lungs. The two lungs concave on top of the diaphragm and the left lung has two lobes while the right lung has 3 lobes. The diaphragm aids in the process of breathing. As demonstrated, the pleural cavity needs to be mimicked in the surgical simulator in order to provide efficiency and accuracy.

Thoracentesis Procedure

In order to properly understand the importance and the requirements of the surgical simulator, we must gain an understanding of the Thoracentesis procedure. The procedure, although seemingly routine, does have certain steps that the surgical simulator must accomplish in order to properly teach the steps.

Thoracentesis is a procedure that is used to drain and collect fluid from the pleural cavity. Fluid removal can either be done to alleviate the problems in the patient, to collect a sample to diagnose the underlying condition causing the need for the procedure or for research.[15] The main cause of requiring such procedure is a pleural effusion. Under normal conditions, fluid enters and exits the pleural space at a constant rate. However, conditions such as cardiac failure, pneumonia, malignant neoplasm, and obstruction of flow can cause the fluid to accumulate into the pleural space.[16]

Figure 4: X-Ray of a pleural effusion[17]

Pleural effusion can be detected using several techniques such as a CT scan, pleural biopsy and X-ray as shown above in Figure 4. The white matter on the left lung indicates a presence of fluid in the pleural space. Pleural effusion may cause dyspnea, cough, and sharp pain making it difficult to breath.[13] Cancer and embolism have also been known to cause such accumulation. Therefore a Thoracentesis is used to obtain the fluid sample for diagnosis and remove fluid from the patient. The amount of fluid can range from very little to about 350 mL.[13] Severity of symptoms increases with increasing fluid accumulation, resulting in a need for Thoracentesis. The procedure is conducted in about 150,000 patients per year due to such prevalence of pleural effusion.[18]

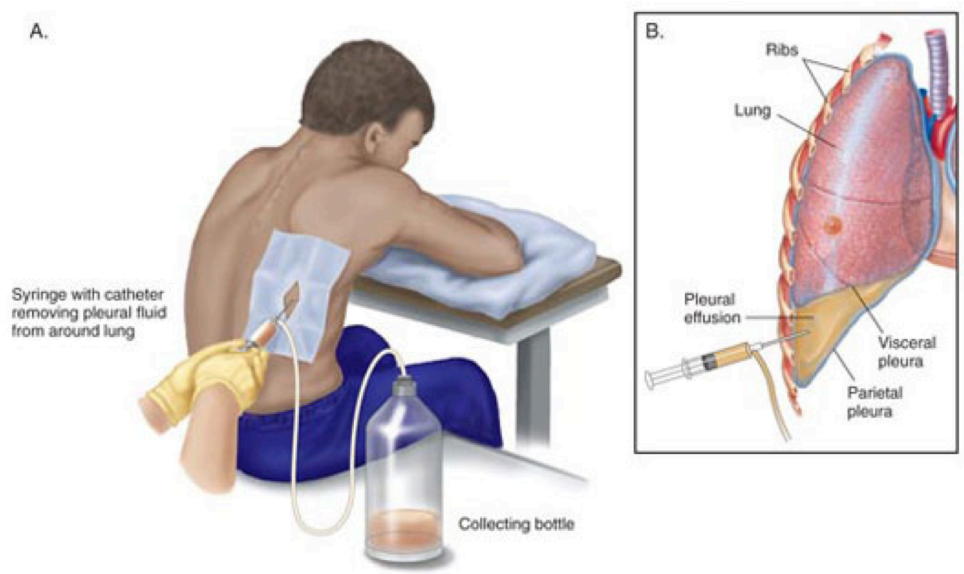


Figure 5: How a Thoracentesis is performed[19]

A Thoracentesis is performed to relieve respiratory distress and makes use of a pre-made Thoracentesis procedure tray containing required materials[15]**.** The patient must be evaluated using the technique mentioned above to determine the site and the side on which the fluid has accumulated. To better access the fluid, the patient is positioned in sitting position as shown by Figure 5. If the patient is unable to sit, he/she is laid down on the side of the bed with the arm raised above the head. The usual site of insertion is the side or the posterolateral side of the back over the diaphragm. The physician confirms the fluid by tapping for percussive dullness and counting the ribs, since the needle is inserted between the 3rd and the 4th intercostal ribs.[15]

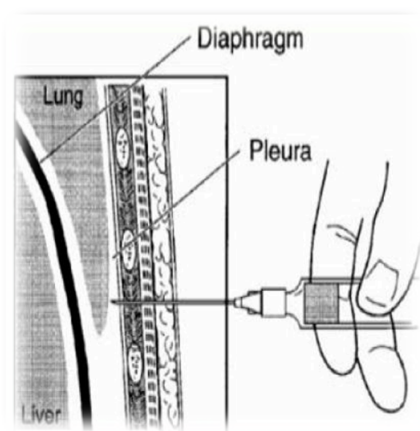


Figure 6: Side view of the insertion of needle through various layers[20]

The area is then anesthetized with a local anesthetic such as lidocaine and a needle is inserted above the rib to avoid hitting the intercostal nerves located beneath the ribs. The 25 or 27 gauge needle is inserted until a "pop" is felt meaning that the needle has penetrated the pleural lining. The plunger is withdrawn to check for proper position of the needle in the pleural space and drainage of pleural fluid. Once fluid begins to drain then the small needle depth is marked with a hemostat to allow for approximation of the insertion of the Thoracentesis needle. The larger 18-gauge needle is inserted to the same depth as the prior needle through the pleural lining and into the pleural space. Once in the pleural space a stopcock and tubing are attached to the needle and fluid is drained and collected.[15] As Figure 6 shows, the needle must penetrate through the skin, the fat layer, the muscle, and the pleural lining, and the surgeon must avoid going too low or far into the cavity and penetrating the lung. The necessary amount of fluid, usually between 100 mL to 350 mL, is drained depending on the amount. The patient then undergoes an x-ray to confirm the removal of fluid from the pleural space.

Although Thoracentesis seems like a simple procedure compared to other high-risk emergency medical procedures, physicians must be trained accurately for needle placement to avoid seriously injuring the patient. Therefore, a surgical simulator is highly desired to allow physicians to practice Thoracentesis repetitively in order to hone their skills and perform the procedure correctly. Nevertheless, there are several surgical simulators on the market that claim to allow physicians to do just that, and although they have had some success, there are certain limitations to their effectiveness.

Surgical Simulators Today

While simulators have been used for the past several years in different settings such as military and aviation, their use in medicine has only recently flourished. There are several companies that produce simulators for various surgical and non-surgical purposes. There are three major types of medical simulators that are in use currently: [21]

Synthetic model

One of the most popular types of models makes use of materials that represent the different parts of the human torso, such as plastic, rubber, ballistic gel, and latex. The models allow a physician to perform various procedures and surgeries that may or may not be invasive.[22] Physical simulators are used to develop skills that are necessary for specific tasks such as cutting, suturing, inserting needles, or clipping.[23] Currently, there are two major models that are being used as surgical simulators, one each from TraumaMan® and SynDaver Labs™.

Figure 7: TraumaMan®[24]

TraumaMan® as displayed in Figure 7 above is an anatomically accurate surgical model with organs that are constructed so that they replicate the geometry of a particular portion of the anatomy. The tissue structure is very realistic as it simulates bleeding and airway response in the pleural space. The model is also convenient and has straightforward maintenance, making it one of the widely used models in the medical field. However, TraumaMan® can be very expensive as it can cost anywhere between $5,000 to $10,000.[25] It also does not contain reusable parts, meaning that the placement of parts can further add to the cost of the model. Although the model is accurate anatomically, current cost and efficiency flaws create a need for a better model.

Another major model that is more anatomically accurate is the one created by SynDaver Labs™ and is known as The Torso. This model is a synthetic physical representation of the human anatomy including skin with fat, each bone and muscle completely articulated organs, a complete digestive tract, and a circulatory system.

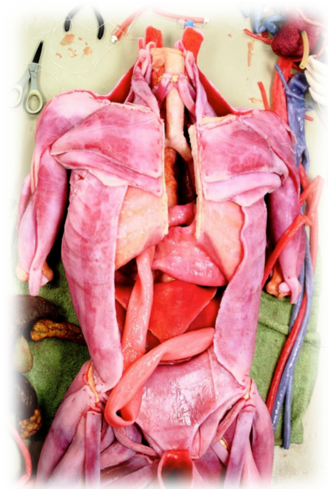


Figure 8: The torso by SynDaver Labs™[26]

As shown in Figure 8, the model is very accurate in representing the human body and is able to provide most of the features and functions of the anatomy. Nevertheless, the model can range from $15,000 to $25,000 depending on the options and therefore can be unaffordable for simulation centers.[27] These models are also not compatible with Ultrasound or MRI and therefore have limitations with diagnostics. Physical simulators must also be reset after each use and included some performance metrics that can be measured by an instructor. Although these models are criticized for their low fidelity and lack of reality, studies have shown that they are very accurate and reliable for training certain surgical procedures requiring hands-on experience.[28] In conclusion, the relatively low cost, physical practicalities, and portability, allow this type of surgical simulator to become the most widely used models for training.

Virtual reality

Until recently, virtual reality simulators were not garnering much attention due to their lack of physical accuracy and anatomical accuracy compared to the operating room. These are computer-based models with specific interfaces that allow the physician to control computer-generated objects.[21] Most developments have been towards laparoscopic and endoscopic surgeries rather than open surgeries, such as Thoracentesis.[28] The reason being is that these surgeries can be easily recreated by virtual simulation because they only comprise of a two-dimensional visual system with limited haptic interactions.[21]

Figure 9: A virtual reality simulator[29]

Figure 9 shows the aforementioned properties of the virtual simulator and displays, its positive features such as the provision tracking of objective and repetitive measurements, errors made, and the efficiency of the task.[30] This allows the physician to assess his/her own skills without the supervision of an observer. Nevertheless, such virtual simulators are unable to reciprocate the anatomical "feel" and physiological accuracy with invasive procedures such as open-organ surgeries, suturing, cutting, and Thoracentesis.

Hybrid

Thirdly, hybrid simulators, as the name suggests, are a combination of both physical and virtual simulators.

Figure 10: Hybrid simulator[31]

They have a physical model that is connected to a computer program that is able to provide visual feedback, as shown in Figure 10 above. The program is able to simulate patient response, physically and physiologically on the model and the computer.[21] In practice, they are mainly used for very specific procedures that require a specific part of the anatomy to be recreated. These simulators are able to provide team response, communication, and more complex tasks, while erasing the line between simulation and the operating room.[32]However, hybrid simulators are very expensive at upwards of one million dollars, and are not as popular due to the high demand of time and effort needed to run them.[21]

In short, the demand for a specific procedure dictates the type of simulator best suited for training the specific procedure. In this case, Thoracentesis is an invasive procedure requiring the draining of the fluid from the pleural cavity. The model must have anatomical and physiological accuracy while providing the physician with the necessary means for training. Although the physical model is an excellent approach to the problem, budget, tools, and knowledge might become a hindrance in creating the perfect model. Nevertheless, the need for simulation-based training ensures that the physicians have practice opportunities for surgical procedures, and it remains an excellent field for further research. In order for physical simulators to become more prominent, it is imperative to validate the skills and the accuracy of the model with real patients.

Project Strategy

Initial client statement

The following statement is an iteration of the preliminary task that was assigned to us by our client, UMass Medical. It can be noted that the statement was kept vague, as to provide our group with an expansive design scope as well to prevent any premature design limitations. Our group would attempt to

"Design a versatile, anatomically accurate human thoracic cavity model, which can be used for surgical training. The model must be affordable, portable, and reusable for various types of medical procedures."

In order to improve the client statement and develop a clearer understanding of the design specifications, the team conducted an interview with clients at UMass Medical. The clients were able to provide limitations on the project and its scope in terms of the MQP. With the aid of the interview, a list of major objectives and functions was constructed to further clarify the design statement. Furthermore, the initial client statement also lacked constraints that needed to be discussed further. After obtaining the necessary objectives, functions, specifications, and constraints, we were able to create a revised client statement that was both thorough and within the scope of our project.

Objectives

There are certain objectives the design must fulfill in order to satisfy our clients and ensure the success of the project. These objectives range from the technical aspects of the design to characteristics of the materials used. Without these objectives, the product will not be optimal in performing the functions necessary for its success. An Objectives Tree in Appendix A illustrates the main objectives of the design. Additionally, these objectives are further subdivided into more specific objectives to aid the group in brainstorming methods to tackle the project. This enables us to break down our main objectives and take a step-by-step engineering approach to reach the ultimate goal of a successful design. The four main objectives of our surgical model are versatility, anatomical accuracy, affordability, and portability. Each of these carries significance; some more than others, but nonetheless contribute to the success of the project. Each of the requirements for the objectives is outlined in Table 1 below.

Table 1: Table of user requirements

Rank	Requirements	Engineering Specifications
1	Include key organs (ribcage, lungs, skin, muscle, fat, pleura)	Yes
2	Anatomically accurate	Yes
3	Penetrable skin and muscle	Yes
5	Penetrable pleura	0.14 mm
6	Resealable skin	Yes (provide >1 access points)
7	Contain fluid	Yes

In terms of versatility, there are two different sub-objectives. One pertains to the ability of the design to allow for the practice of several different surgical procedures. In order to successfully complete the model, the medical students must be able to perform various emergency procedures such as Thoracentesis, pericardiocentesis, needle decompression, and IV cut down. These procedures all involve needle insertion, so we must be able to replicate the various aspects of the thorax to give the user accurate landmarks for needle placement. Additionally, the ability to perform different procedures will eliminate the need for multiple models. This will reduce the model cost and eliminate the need for multiple models, since the design will accommodate each of the stated emergency procedures. In order to achieve such a task, the model must also have various functional parts. This means that the model must have the major aspects of the thorax, such as the skin, ribs, lungs, heart, and other major features. These parts must also be functional in the sense that they must accommodate for the performance of realistic surgical procedures. The parts must exhibit biological properties, which will aid medical students to practice techniques such as decompression of air and fluid and blood presence. The functional parts must also be easy and inexpensive to replace so the simulator can be reused multiple times, increasing the lifespan of the model. This will make surgical practice extremely reproducible, which is ideal in a teaching environment. It is also important that several students are able to learn the procedure in succession. Complete replacement of the model would be incredibly inefficient in a training setting, as students would have to wait much longer for hands on surgical training. Thus, one of the challenges presented is to use replaceable or resealable parts that may be damaged during a surgical procedure. Ultimately, the goal of this objective is to save time and money by creating an efficient model with easily replaceable parts, to allow multiple surgeries on one model.

Another major objective of the design is to be anatomically accurate. If the design is to portray the human thoracic cavity, from the bottom of the neck to the top of the diaphragm, and allow for accurate surgical training, it must be as similar to the human body as possible. Specifically, the major parts the product needs to comply with are the thoracic cavity, the skin properties, and surgical complications. From our research and client discussions, the team decided the model must be around 30 in. in height, 22 in. in width, and 11 in. in diameter.[1] These are the average dimensions of the thorax of an adult male. In terms of the thoracic cavity, the model must be contoured similarly to the human body and have all of the physical properties that a thorax possesses. Additionally, the model must comply with the skin properties of the body. Since the skin is a very complex organ, it is difficult to replicate. However, in order to allow for proper training and puncture of the skin for the procedures, the model must have properties similar to the skin. With the aid of these properties, the model will be more accurate and anatomically aiding in the procedures. The ability to portray accurate fluid and air containing spaces is also an important aspect. This will help introduce the student to the procedure of drawing fluid. It will help accurately simulate the force needed to draw fluid carefully and efficiently, as well as how quickly fluid will flow through the needle once the puncture is made.

Although the above two objectives are important, since this is a surgical simulator, the model must also be able to accurately portray the complications that may arise from surgery. The medical students are proficient, but they are not perfect and they are bound to make mistakes. In order to successfully aid them in practicing, the model must be able to notify the student that they have made a mistake during the procedure. The major problems that we are focusing on include accurate bleeding, punctured lungs, skin tearing, and fluid accumulation. In terms of accurate bleeding, if there is a cut or a misstep performed by the student, the model must bleed as the human body would. This means that it must spurt, flow, or ooze depending on the part of the body. This will allow the student to get used to emergency situations since most of the time the patients are bleeding as a cause of the trauma. Punctured lungs are also a major complication that occurs due to trauma and errors in surgery. If the lung is punctured, the airflow must be accurate so that the student is able to treat it accordingly. This will be taken care of by making use of an air pump that allows for inflation and deflation of the lung. Another objective of the model regarding surgical complications is the simulation of proper skin tearing when an incision is made. Incisions are a major part of surgeries, and in order to become a functional surgical model, it must have appropriate skin tearing. In order to accomplish this we need to find a product that has similar elastic, tearing, and physical properties as the skin. Fluid accumulation during surgical complications is a major objective in making the product anatomically accurate. When a surgery is performed, the student may accidentally cut a part of the thoracic cavity, which may fill the cavity with fluid. This is a common complication that the student must correct in order to keep the patient healthy. So our model needs to pump fluid in such a fashion that it allows it to accumulate and drainage to occur. From physiological properties to surgical complications, anatomical accuracy is the most important aspect of creating a surgical simulator for emergency procedures. The accurate portrayal of the human thoracic cavity will make the model function and helpful in surgical training.

Nevertheless, there are also smaller objectives, which must be accommodated into the model to make it functional and specific to our clients at UMass Medical. The model must be affordable when compared to the models in use currently. The current models range from $5,000 to 25,000[2]. This means that it is very difficult for a training class at a medical school to replace the model or buy several models in bulk. This goes along with the replaceable parts, which will cut down the cost and eliminate the need for bulk models as well. Nonetheless, the model may be a preliminary design with basic features, but it will be significantly cheaper than the current models offered on the market. We will try our best not to compromise the functional capabilities of the model for the price though. In order to be inexpensive, the model must be made of cheap materials. Since we lack the resources to obtain skin grafts and other anatomically accurate polymers, we will need to create a model from cheap parts such as basic polymers, plastics, and ceramics. This will allow us to easily reproduce the model whenever necessary, while also holding the inexpensive aspect of the cost.

Last but not least, the cheap, anatomically accurate surgical simulator must also allow for portability. The model must be moved from place to place depending on the surgery performed or the class it is needed for. Therefore, one must easily be able to transport the model from one place to another. We wish to complete this objective by making the model lightweight and with materials that do not add too much to the mass of the model. Additionally, we also wish to increase the portability by only taking care of the necessary parts of the model and making them out of parts that do not hinder the movability. We might also include a carrying case or straps on the simulator in order to make it even easier to transport longer distances for the ease of the students. Portability becomes an objective since it allows for our design to be moved and used by several groups of people.

Regardless of the objectives the team came up with, there had to be a way to compare them to each other and rank them in the order of importance and necessity of the complete functionality of the model. The reason being is that through this process, we would be able to assess which objectives we really need to focus on and which ones we can compromise to sustain the integrity of the more important objectives. The pairwise comparison chart in Appendix B allows for such comparison of the objectives. In this chart the objectives were written in across both rows and columns and compared to each other. A score of 1 was awarded to the objective with a higher importance and a score of 0 was awarded to the objective with the lower importance, in comparison. As it can be noted, anatomical accuracy and versatility received the highest scores, of 5 and 4 respectively. This means that these objectives are the major components of the design and we must include them in our model to have it be successful. A surgical Thoracentesis model must be anatomically accurate to portray all of the physiological aspects of the human body and it must also be versatile to allow for a broad spectrum of emergency surgical procedures to be performed. The team must focus on designing a model according to these objectives primarily. On the other hand, portability, specifically lightweight and composition with cheap materials received the lowest scores of 0 and 1 respectively. Although the surgical model needs to be portable and composed of cheap materials, they are on the lower end of the importance scale. We will try to accomplish them however; we need to accomplish the more important ones first. The pairwise comparison chart allowed us to see the most important objectives and tailor our research and design to make sure they are reached. The objectives presented to us by the surgeons at UMass Medical provided us with a clear idea of the design we need to accomplish in our MQP. Ultimately, it allowed us to create a surgical model, which will hopefully aid the surgeons greatly.

Constraints

As with every project there are certain constraints that must be accounted for while creating a new design. Two of the biggest constraints for our team are budget and time. We would like to stay within our estimated budget of $500 to $700 and we would like to start testing a potential prototype by the beginning of March. These are two very generic constraints that all MQP teams must observe. One of the biggest constraints is achieving an end cost that is lower than present models. The group has established a target cost within the range of $500 to $700. Along with price there are many more constraints specific to our project that must be taken into account.

After talking to our advisors at University of Massachusetts Medical School about our specific Thoracentesis model, it was determined that one of the biggest constraints was going to be based on construction materials. Since there are many specific and unique viscoelastic properties of human skin, we are very limited as to materials for our model. We must find a material that closely mimics the tensile strength, elastic modulus, and texture of human skin. This is crucial to our design because, as a surgical simulator, our device needs to be as anatomically accurate as possible. This would give the surgeon a more realistic surgical experience, which would be incredibly beneficial for when he or she starts operating on real patients. Another material limitation that we will encounter is the fact that our model has to be ultrasound compatible. This means we are limited to materials that have similar material properties to soft tissue.

Lastly, size and weight are two constraints that also must be considered. The dimensions of the human torso are crucial for us to replicate because of the certain landmarks doctors use during surgery. We need to make these dimensions as anatomically accurate as possible. This will give the surgeon a good idea of where he will be inside the body. Without this anatomic accuracy, the device would be useless. We have decided the dimensions of our model should be around thirty inches in height, twenty-two inches in width, and eleven inches in depth. However, we are not limiting ourselves to these dimensions. We also must make the model lightweight so that it can be transported from room to room very easily. All of these constraints need to be taken into account in order for us to have a device that will satisfy our client, which of course is the ultimate goal in our project.

Revised client statement

After carefully reviewing our objectives and justifying our realistic goals in a team meeting, we decided to revise our original client statement to more accurately depict what we decided the project should ultimately accomplish. One of the areas we decided to focus on was the nature of surgical procedures that could be performed on our model. We decided to restrict the focus of our device to the Thoracentesis procedure only. This is mainly due to the time and budget restrictions the group was presented with. It is much more feasible to create an accurate surgical simulator when only one procedure is focused upon. The clients and team decided to narrow the scope of the project to the Thoracentesis procedure due to high cost and low availability of current models. This brought us to our revised client statement, which is:

"Design an anatomically accurate human thoracic cavity model, which can be used to teach the Thoracentesis procedure. The simplified model must be affordable, portable, and reusable. The focus of the model is to simulate accurate fluid flow, tissue properties, and encourage proper needle placement."

Project approach

After revising the objectives based on the client's needs, the scope of the project was narrowed down. This section identifies the approach and development of the model, which will be used by surgeons to develop the skills necessary to perform Thoracentesis. We decided to eliminate the diagnostic aspect of the procedure that includes obtaining a chest X-ray and palpating the back. This is because we wanted to replicate the steps involving the fluid drainage itself and not the pre-diagnosis of the condition. It is more important to allow training of the procedural steps themselves than to provide repetition of the diagnostic steps because they do not directly harm the patient. The goal as stated in the client statement is also to allow for training of the therapeutic steps so that the medical professional is able to hone his/her skillset. When designing this model, the client's needs must be satisfied.

Client's needs

- Affordable
- Portable
- Versatile
- Anatomically accurate

In order to ensure that all of the client's needs are met, work will be divided according to the following project phases:

Preliminary design phase

This phase will allow us to participate in meetings with the client to discuss options available for the Thoracentesis model. The discussions will enable us to develop a manageable design that will fulfill the requirements given to us. Once the final design is determined, we will establish the specifications for the model, which will aid us in the development of the preliminary model.

Construction phase

In order to achieve our objectives we must address the constraints:

- Budget
- Materials
- Size/weight

To create an accurate surgical simulator, the correct materials must be used to simulate all of the properties of the human body. The group has composed a list of engineering properties for specific materials that will aid in the conceptualization of alternative designs for the model presented in Table 2. The chart lists the properties for each of the components of the human thorax and compares them to materials that have been shown to mimic the various parts of the cavity. Each of the material properties is chosen to exemplify the quantitative measurements that we believe are best representative of the specific anatomical feature. With these specific properties, we are able to narrow our material choices for each part and create alternative designs tailored towards the objectives of the model.

Table 2: Engineering values for possible materials

Adult Human Male

LUNGS

	Human Tissue	Speed Bag Bladder (latex)	Hot Water Bags (Natural Rubber)	Ballistic Gel	Balloon (Latex)	Foam
Elastic Modulus (GPa)	6.6 x 10^{-6} [33]	0.0006-0.0011[34]	0.031[35]	0.0001-0.00015[36]	0.0006-0.0011[34]	1.4[37]

MUSCLE/FAT LAYER

	Human Tissue	Neoprene	EPDM	Ballistic Gel	Foam
Needle Penetration Force (N)	35[38]	5[39]	35-45[35]	N/A	N/A
Elastic Modulus (GPa)	3.2-9.6 x 10^{-5} [33]	0.028[35]	0.00047[35]	0.0001-0.00015[36]	1.4[37]
Density (g/cm^3)	1.04[33]	1.23[40]	1.22[41]	1.06[33]	0.013-0.04[42]
Durometer	30.1[43]	30-95[35]	40-90[35]	N/A	50[44]

RIBS

	Human Tissue	PVC	Metal	Wood
UTS (MPa)	124.2[33]	82[45]	860[34]	40-50[34]
Elastic Modulus (GPa)	13.9[33]	2.5-4.1[45]	180[34]	9-13[34]

SKIN

	Human Tissue	Ballistic Gel	Silicon Rubber	Latex
Elastic Modulus (GPa)	0.0015[33]	0.0001-0.00015 [36]	0.010 [35]	0.0005[46]
UTS (MPa)	0.272[47]	0.000158[48]	45-55[49]	0.028[46]
Needle Penetration Force (N)	2[50]	N/A	2.2[51]	3.1[50]

PLEURAL LAYER/CAVITY

	Human Tissue	Plastic Bag	Latex Layer	Shrink Wrap	Cloth	Water Bladder
Needle penetration Force (N)	1.0[50]	0.3[52]	3.1[50]	0.3[52]	60-120[53]	2.0[33]

Alternative Designs

Needs analysis

Primary requirements

Include parts of the thoracic cavity

For the surgical simulator to be considered effective, it must be anatomically accurate. Every organ that is involved in the procedure must be present in the model. The procedural steps for Thoracentesis (As shown in Appendix D) determine which components of the thoracic cavity are necessary. Appendix E analyses each step of the Thoracentesis procedure and determines the overview and more specifically the scope of each step to determine which organs are truly needed to make the model accurate. The parts of the thoracic cavity that are needed for a Thoracentesis procedure include the ribcage, lungs, skin, muscle/fat layer, pleural cavity and pleural lining.

Sets of technical requirements were established for each organ. The size of the model was based on the average dimensions of a male torso as shown in Table 3. These measurements determined the desired measurements for the thorax.

Table 3: Dimensions of the thoracic cavity[54,55]

Characteristic	Dimension
Height	32 cm
Width	32 cm
Depth	24 cm
Average Circumference	95 cm
Thoracic Cavity Volume	25 L
Pleura Thickness	0.15 mm (2)

The lungs are incorporated into the model as placeholders for which the dimensions are shown in Table 4 below:

Table 4: Dimensions of the lungs[56]

Characteristic	Dimension
Total Lung Capacity	6 L
Tidal Volume	0.5 L
Inspiratory Reserve Volume	3.3 L
Expiratory Reserve Volume	1.0 L
Inspiratory Height	23 cm
Expiratory Height	95 cm
Respiratory Rate	12-20 Breaths/min

The lungs are needed in the event that the user performs the procedure incorrectly and penetrates the needle too far. If this were to occur in an actual Thoracentesis procedure, the needle would collapse the lung. The doctor is made aware he or she has collapsed the lung when either air instead of water is drained or when the patient is in severe pain. Because our model will not be able to simulate patient sensations, we needed to incorporate something that would allow for air drainage. It was important to find something that was similar in size to a lung because there are numerous places the lungs could be punctured.

Penetrable skin and layers

Because Thoracentesis involves the penetration of a needle through the skin, muscle and fat between the ribs, it is necessary for the model to be comprised of materials that allow for such penetration. We wanted to incorporate different materials for the various layers because certain materials could mimic the properties of the individual layers better than others.

Resealable skin

To ensure the users get the most of the model it is necessary to increase the longevity of the simulator. By choosing a material for the skin that does not show penetration marks, the model allows for multiple students to practice the procedure. If penetration marks are visible on the skin layer it defeats the purpose and makes the training easy because the student will know exactly where to insert the needle.

Contain fluid accumulation

The main goal of a Thoracentesis procedure is to remove the accumulation of fluid from around the lungs, so it is necessary that our model both contains this fluid and is capable of having the fluid drain.

Collapsible lungs

Having a collapsible lung is a must have requirement. Although lungs are not vital organs in performing an emergency Thoracentesis, they are needed in case the medical student messes up this critical procedure. The student needs to be able to insert the needle into the pleural cavity without going too far and puncturing the lung. If the lung is punctured and air is drained, then the trainee knows the procedure was not preformed accurately.

Secondary requirements

Affordable

It is imperative to make sure that the final product is affordable. In terms of designing the simulator, our costs will be determined by the amount of materials we use to manufacture our organs and the cost of each of those materials. Current models cost upwards of $5,000; we want our simulator to cost, in total, from $500-$700.

Reusable and minimal replacement parts

Each component of the simulator must be reusable to differentiate it from the expensive models currently available. If the components in our model can be used to simulate a procedure multiple times, it would increase the longevity of the device and reduce the cost. Based on the reusability of other simulators, we want our simulator components to be able to be reused more than five times.

Easily transported

For convenience, the simulator should weigh no more than 15 pounds, which was found to be the average weight of other simulators.

Easy to manufacture

In order for our product to be successful, it must be easy to replicate. This will reduce manufacturing and labor costs and allow for training clinics to purchase numerous simulators for multiple students.

Table 5 below summarizes the primary and secondary requirements mentioned above:

Table 5: Primary and secondary requirements

	Requirements	Technical Requirements	Ranking
Needed Requirements	Include parts of thoracic cavity: Ribcage Lungs Skin Muscle Fat Pleural Cavity Pleural Lining Heart Diaphragm Sternum	Must cover thoracic cavity See Appendix F	1
	Anatomically accurate	See appendix F	2
	Penetrable skin and layers	Yes	3
	Penetrable Pleura		5
	Resealable Skin	Yes – liquid rubber or multiple access points	6
	Contain Fluid	Yes – Using balloon filled with water/fluid	7
	Lungs must be collapsible	From fully inflated to deflated	8
Can Have but not necessary	Affordable	< $500	9
	Minimal replacement parts	≤3	10
	Reusable	≥3	11
	Easily transported	Less than 25 lbs.	12
	Easy to manufacture	< 10 materials	13
	Meet the specification of other devices	Yes	14

Functions

In order to create a proper Thoracentesis surgical simulator model, there are certain functions that the model must perform. These range from the materials to the actual simulation of surgery. Three major tasks that the model must include are: aid in surgical training, anatomical accuracy, and ultrasound compatibility. The following Figure 11 is a function-means chart created by the group to aid in the fabrication of conceptual designs.

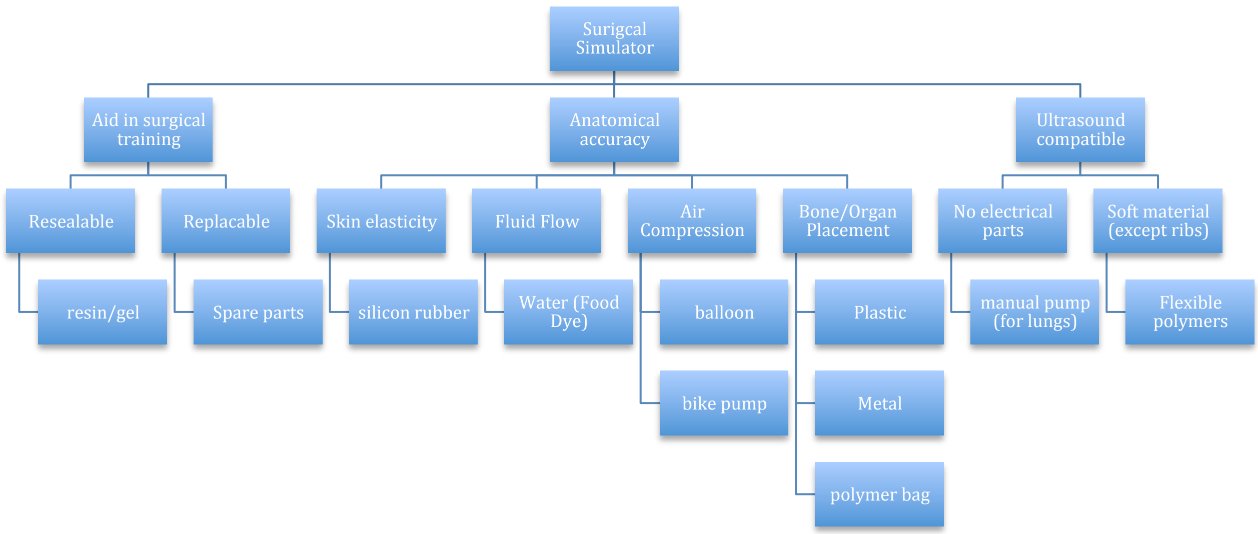


Figure 11: Function Means Chart

The primary job of the surgical simulator is to aid the medical students in surgical training. Specifically, being able to perform emergency procedures is the most important goal of the new model. This goal can be broken down into several functions our model must implement. They are resealibility and replaceability. It is important for the model to allow for resealibility because the medical student must be able to perform the procedure several times within the model. This can be done one of two ways. A thermo-reversible resin or gel could be liquefied and remolded into our model, or an adhesive like rubber cement could be applied to the punctured material before or after surgery. The replaceable aspect is similar in the sense that once a part of the model has been used extensively, it must be able to be replaced with ease, without having the need to buy a separate model altogether. For example, if the model has gone through many cycles of Thoracentesis training, the pleural cavity, skin, or muscle may have to be replaced. Therefore, we will try to use easily obtainable material that is inexpensive and easy to replace.

While the surgical simulator must allow for aid in surgical training, it must also provide anatomical accuracy for the trainees. Generally, surgeons want to practice on a model that is anatomically accurate when compared to the human body, with all of the organs, ribs, and other physiological features in the right places. With this model, we wish to allow for such accuracy so the surgeons in training get the most out of the procedures and they are able to learn perfectly. If the model did not allow for anatomical accuracy, it would be of no use regardless of other functions, because it would not be similar to the human thoracic cavity, nullifying the goal of our project. There are certain functions that are specific to the accuracy of the model, which include: skin elasticity, fluid flow, air compression, and bone/organ placement. Skin elasticity is a major property that allows the model to perform anatomical accuracy. Since the skin is the organ that needs to be penetrated in order to perform most emergency procedures, the model must accommodate the accurate stretching, breaking, and elastic properties. This is important because it will allow the accurate display of properties, which is important for the surgeon seeking to gain knowledge from the model. This can be accomplished by using any cheap skin substitute polymer such as silicon or latex rubber. Similarly, the model must also permit accurate fluid accumulation and flow. This can be accomplished by using water with yellow food coloring. It is also important to have the model provide accurate air compression in the lungs. Since the lungs contain air in the human body, our model must portray exactly that to fulfill the function of anatomical accuracy. When the lung is punctured, air must be released so the surgeon knows he is in the wrong spot. Furthermore, as part of anatomical accuracy, proper bone and organ placement is also necessary. The model must accurately show the bones (ribs, vertebrae etc.) and organs (lungs, heart etc.) in their proper places. The reason being is that the surgeons must be able to accurately practice the procedure. If the placement is not accurate, it may become an erroneous mistake for the surgeon, as he/she will be unable to practice the specific procedure. By accommodating the model with specific physiological properties to permit anatomical accuracy in the body, we will be able to provide a more accurate and better simulation of surgery during training.

The final major function of the surgical model is to promote ultrasound compatibility. This is an important function because, during the Thoracentesis procedure, needles are commonly guided with the use of ultrasound imaging. In order to accomplish such functionality, the model must not contain any electrical parts that may interfere with the ultrasound and it must have mostly soft tissue besides the bone to allow for better viewing images and prevent distortions. We wish to incorporate such aspects in order to satisfy the needs of the surgeons that require the use of ultrasound as a medical technique. This will more accurately simulate a real step-by-step Thoracentesis procedure.

Design alternatives

With much group collaboration, four alternative designs ideas were created for our surgical simulator. We have nicknamed them the simulation model, the box model, the ballistics gel model, and the plastic model. Since our design was constrained by the shape and properties of the human torso, it was difficult to come up with conceptually different proposals. Therefore, most of the alternative designs vary through use of different materials.

"Simulation model"

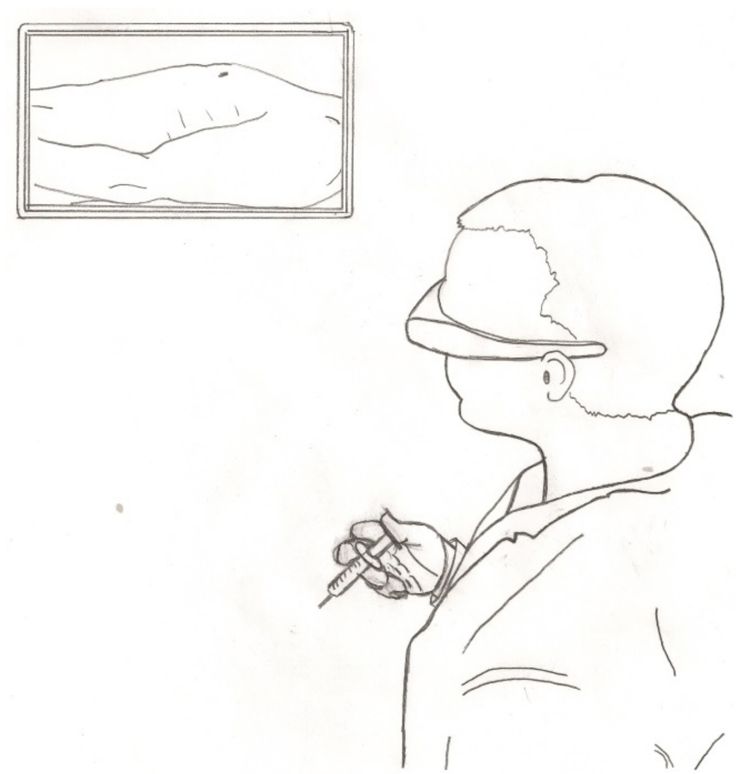


Figure 12: Simulation model sketch

In our simulation model, the doctor will view a virtual patient through an eyepiece. This eyepiece will be attached to two mechanical arms that are motion sensitive and have plastic extensions to simulate the feel of surgical tools. The student would proceed to use the tools as he would in an operating room, following the normal protocol for a Thoracentesis. The mechanical arms would pick up the motion and relay a signal to the graphical simulation on the computer screen, which would have the image of the virtual patient. If a surgeon were to make a mistake, the program would notify him or her with an alarm. This entire device will be attached to a television monitor so that a professional can evaluate the surgical intern. Although this model has the potential to be one the most accurate simulation device, it would not be one of our more feasible options. As our project team lacked sufficient experience and knowledge in electrical engineering or programming, two skills that are required to make such a model, we did not pursue this design alternative. We also lacked the funds to be able to execute a model like this.

"Box model"

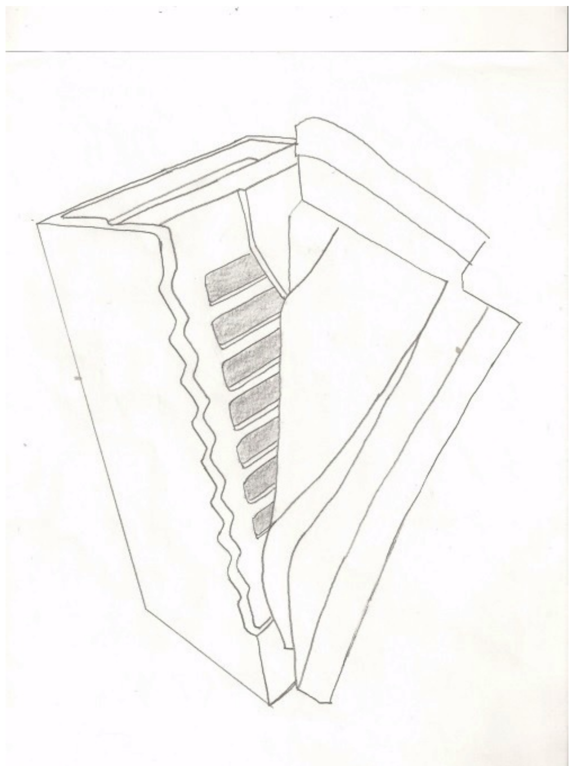


Figure 13: Box model sketch

This model is basically half of a torso enclosed in what looks like a box. The outside of the model is coated with silicone rubber to simulate skin properties. Inside the box there is a set of twelve anatomically accurate ribs made out of PVC. Behind the ribs is a sac made out of latex and filled with fluid. This is what the surgeon will try to reach with the needle. The top of the box can be opened so that the sac filled with fluid can be easily replaced. The front of the model where needle insertion occurs can also be peeled off and replaced. The problem with this model is that it only allows the surgeon to practice a Thoracentesis. One of our goals in this project is to allow the performance of various emergency procedures on this one model. The box model would not allow this.

"Ballistics gel model"

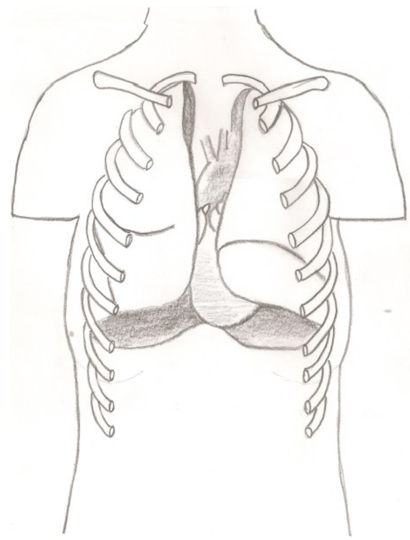


Figure 14: Ballistic gel model sketch

This model is a mold of the human torso made from ballistics gel. It will contain 24 plastic ribs, a sternum, vertebrae, latex synthetic lungs, and a latex synthetic heart. The lungs will hold fluid for the Thoracentesis procedure. We will make a series of tubes filled with corn syrup with red food coloring to make it as realistic as possible. There will be an open compartment at the bottom of the torso to replace the lungs and heart once they are drained. Since ballistics gel is thermo-reversible, it can be melted and cooled an unlimited amount of times. This way, refilling the hole with the liquid gel and having it cool and harden before the next procedure is performed can easily replace the holes from the needle. This design would be resealable, affordable, simple to manufacture, portable and ultrasound compatible. The only problem we may encounter is the fact that ballistics gel is translucent. One way we could solve this would be to add some dye to make it more opaque.

“Plastic model”

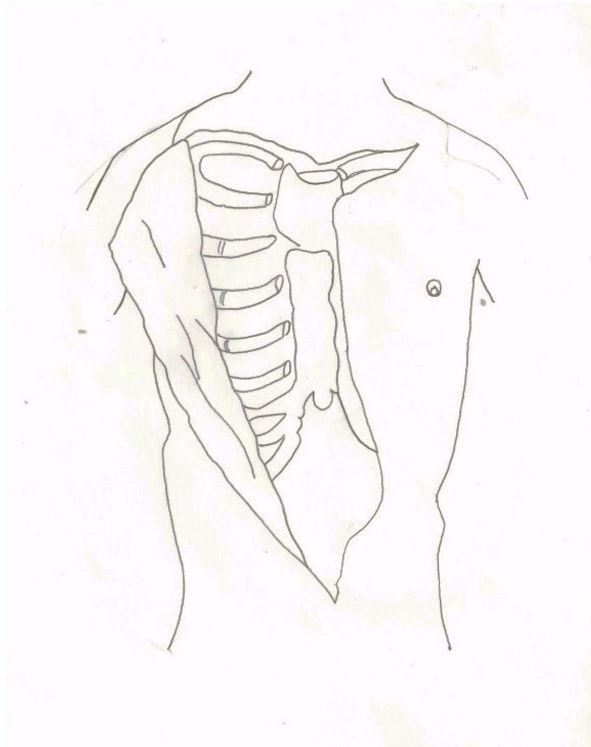


Figure 15: Plastic model sketch

This model contains 14 ribs made out of PVC and a sternum and vertebrae made out of wood. We would then use EPDM and latex rubber to coat the rib cage. We would use speed bag bladders as placeholders for the lungs. This model would be very similar to our ballistics gel model but made out of a different material. This model would not be as resealable, but the needle penetration marks should be small enough where they will not be visible in the latex rubber. The model would be open at the top and bottom so the lungs and pleural cavity can be removed easily.

Design evaluation

After careful analysis and deliberation by group members, we composed a design evaluation matrix in Table 6 to identify a final conceptual design which will be taken to the manufacturing and experimental phases of our project. Each of the design objectives was weighted according to significance and need as decided by the group members and clients.

Table 6: Design evaluation matrix

Design Constraints		Virtual Simulator		Box Model		Ballistic Gel		Plastic Model	
Cannot cost more than $1,000		✗		✓		✓		✓	
Ultrasound Compatible		✗		✓		✓		✓	
Weight		✓		✓		✓		✓	
Replicate human torso		✓		✓		✓		✓	
Design Objectives	**Weight**			Score	Weighted score	Score	Weighted score	Score	Weighted score
Various functional parts	15			0.8	12	1	15	1	15
Thoracic cavity	35			0.1	3.5	1	35	1	35
Skin properties	3			0.6	1.8	0.9	2.7	1	3
Surgical complications	5			0.3	1.5	0.9	4.5	0.7	3.5
Affordability	30			0.8	24	0.7	21	1.0	30
Easily transported	2			1	2	0.7	1.4	0.8	1.6
Resealable	10			0.5	5	1	10	0.8	8
Total	100			C	49.8	B	89.6	A	**96.1**

Constraints of our model were evaluated first. Since the virtual simulator did not satisfy all of the constraints, it was eliminated from contention for our final design. When approaching objectives, each was given a weight to correspond to the importance of said objective. These objectives were carefully reviewed by the team and clients to establish an accurate weight for the model. Each alternative design was given a score ranging from 0 to 1 depending on how well it satisfied the objective.

The group chose the accurate simulation of the thoracic cavity as the most important objective since we decided it had the largest impact on teaching a student how to perform a Thoracentesis. Accurate landmarks for needle placement seemed to be the most crucial component leading to a successful surgical trial. This was closely followed by affordability because a significant goal of this design was to minimize the cost of a successful surgical simulator. The presence of different functional parts followed affordability as the group decided a distinction of different layers, inflatable lungs, and pop of the pleural cavity would give the surgeon the best feel for the depth of the needle. The functional parts objective was followed by resealability. This is a major objective due to the fact that the procedure must be performed multiple times on one model. This will cut the cost of replacement parts as well as increase the lifespan of the model. Resealability was followed by the surgical complications objective. Since this is a fluid drainage procedure, the only complications that arise are from inaccurate needle placement. Anatomical accuracy and functional parts already play a key role in the encouragement of proper needle placement. Therefore surgical complications did not seem as significant. The skin properties objective was next on the list. Since it is such a thin layer for the needle to penetrate and had nearly no impact on the success of the procedure, it scored a much lower rating. Portability ranked last in our matrix. This is because, according to our client, the model would most likely reside in the simulation center at UMass Medical and would not have to be moved often.

Tentative final design

According to the design evaluation matrix, the plastic model scored the highest ranking, followed by the ballistic gel model and then the box model. The plastic model seemed to have the most potential success out of all of the conceptual designs. It should have high anatomical accuracy, while possessing many different functional layers. It should also possess resealable parts, be inexpensive and very portable. Now that we have decided which design we will pursue, materials and specifications must be identified.

Decisions

Now that a final tentative design had been established, the group had to carefully evaluate which materials would be used to most accurately replicate the human torso. The model was separated into six separate components. They were skin, muscle/fat, ribs, lungs, pleural lining, and pleural fluid. The engineering properties described in the previous chapter were most representative of the significance of each part with relevance to our model were compiled in a table. Materials we believed exhibited these necessary properties were then matched up against one another in a quality test to determine the final materials the group would use to build the model. The scale ranged from 1 to 9 depending on how while the material satisfied the criteria, which was weighted in order of significance.

Material selection

Ribs

The primary function of the ribs is to allow the user to determine where to perform the Thoracentesis procedure. The ribs must be accurate in size and spacing to provide landmarks for the patient to perform the procedure. We considered several material choices as seen in Table 7:

Table 7: Material selection for ribs

Selection Criteria	Weight	Material		
		PVC	Metal	Wood
Anatomically accurate	9	9	8	7
Feels Real	7	9	2	9
Affordable	6	4	4	9
Minimum Replacement Parts	5	9	9	9
Reusable	4	9	9	7
Transportable	3	9	4	9
Response to Fluid	2	9	6	1
Ease of Manufacturing	1	2	4	3
Total Score		**368**	283	358

Metals were eliminated because they were above our budget and difficult to manufacture into the needed shape. PVC was ultimately chosen because it is already shaped with a circular cross section.

Lungs

The lungs primary function is to collapse in the event that it is punctured. Because the lungs are placeholders, we wanted something cheap so if it is punctured it could be an affordable replacement. Table 8 shows the material selections for the lungs and as shown by the scores, the speed bag bladders were the obvious choice. Additionally, each of the other materials was disregarded due to anatomical accuracy, affordability, and reusability.

Table 8: Material selection for lungs

Selection Criteria	Weight	Materials				
		Speed Bag Bladder	Hot water bags	Ballistic Gel	Balloon	Foam
Anatomically accurate	9	9	8	9	7	8
Feels Real	8	9	9	9	6	7
Mimics Breathing with aid of air pump	7	9	9	6	1	3
Affordable	6	9	7	4	9	9
Minimum Replacement Parts	5	9	9	1	9	9
Reusable	4	9	9	1	3	9
Transportable	3	9	9	4	9	9
Ease of Manufacturing	2	9	9	5	9	9
Response to Fluid/Puncture	1	9	9	1	2	3
Total		**405**	383	251	276	332

Skin

For the skin component we have chosen to use latex rubber. Table 9 below shows the rankings of each of the materials considered.

Table 9: Material selection for skin

Selection Criteria	Weight	Types		Materials			
		Moldable	Material with access points	Ballistic Gel	Silicon Rubber	Latex	Leather
Anatomically accurate	10	8	9	9	9	9	9
Allows access to ribs	9	9	9	9	9	9	9
Feels Real	8	9	9	9	8	9	6
Reseals to an extent	7	9	7	9	7	8	8
Affordable	6	3	8	4	7	9	2
Minimum Replacement Parts	5	0	9	1	4	6	1
Reusable	4	0	9	1	5	7	1
Transportable	3	3	9	4	9	9	6
Response to Fluid	2	2	9	2	9	9	7
Ease of Manufacturing	1	9	8	4	9	9	7
Total Score		336	**474**	359	420	**465**	335

As it can be noted, materials with an access points were reusable and much easier to use as skin when compared to a molding. Furthermore, latex was the optimum choice because of its anatomical accuracy. All of the other materials did not compare in terms of the physiological appearance of the skin. The skin encases the muscle/fat layer and provides access to the ribs and the thoracic cavity. According to feedback from Dr. Heitmann at UMass Medical, it fulfills the critical user specifications of feeling real and being anatomically correct. The latex rubber was also an affordable material and it can withstand repeated punctures without visible signs of wear.

Pleural cavity lining and cavity

Table 10: Material selection for pleural lining and cavity

Selection Criteria	Weight	Materials				
		Plastic Bag	Latex Layer	Shrink Wrap	Cloth	Water Bladder
Anatomically accurate	9	6	8	9	6	8
Feels Real	8	7	8	7	5	9
Penetrable	7	9	9	7	8	9
Affordable	6	9	8	9	8	9
Minimum Replacement Parts	5	9	9	6	8	9
Reusable	4	7	8	6	6	9
Transportable	3	9	9	9	9	9
Ease of Manufacturing	2	9	8	9	8	9
Response to Puncture	1	9	9	8	7	9
Total		354	375	347	312	**404**

Table 10 above shows that the water bladder is the best choice for the pleural lining due to its penetrability, anatomical accuracy, and the ability to hold the fluid. Thoracentesis removes the excess water that accumulates in the pleural cavity against the lungs. In order to mimic the pleural cavity and lining we needed something that could contain water as well as provide a "pop" that surgeons encounter when the needle passes through the pleural lining. The 20-gauge needle easily penetrated through plastic bags, latex layers and shrink-wrap, so we needed a thicker material. After brainstorming and experimenting on numerous materials, a water bladder proved to be the best solution.

Muscle Fat layer

Table 11: Material selection for muscle and fat layers

Selection Criteria	Weight	Materials			
		Neoprene rubber	EPDM Rubber	Ballistic Gel	Foam
Anatomically accurate	9	9	9	8	6
Feels Real	8	9	9	8	5
Penetrable	7	8	9	8	7
Affordable	6	8	8	7	7
Minimum Replacement Parts	5	8	9	5	7
Reusable	4	7	8	4	6
Transportable	3	9	9	9	9
Ease of Manufacturing	2	9	9	5	8
Total		370	**386**	312	287

The muscle and fat layer had to be penetrable and mimic the elasticity of the layers of human fat. EPDM, as shown in Table 11 was found to have a similar consistency, along with the feel of the tissue. Since it was much easier to combine the adipose and the muscle layer, the team decided to use one layer to represent both of the tissue layers.

Model of conceptual final design

After all of the materials had been determined, the group decided to model the design in SolidWorks® in order to get a better understanding of what manufacturing techniques could be used to build the model. Each of the drawings has been separated by the anatomical component.

Ribs

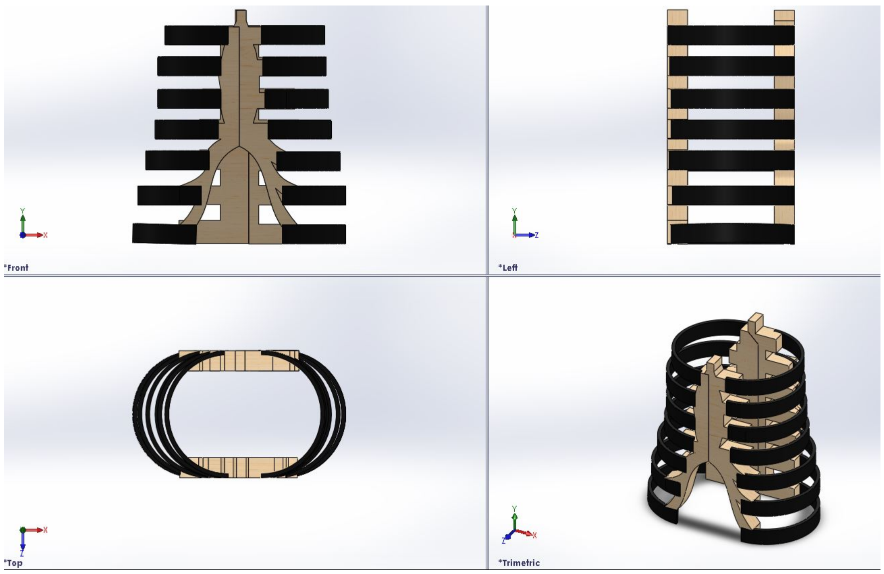


Figure 16: Cad model of ribcage in 4 different views

Lungs

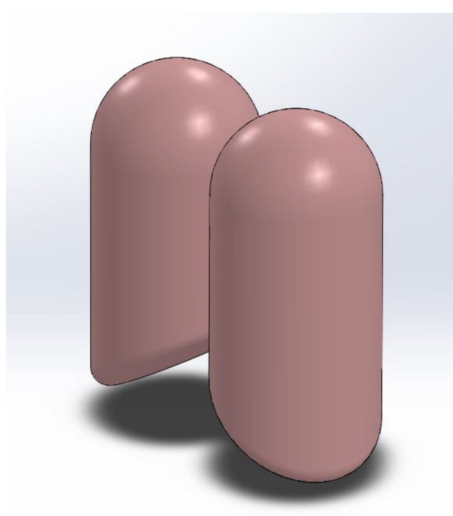


Figure 17: CAD model of lungs in transverse view

Skin

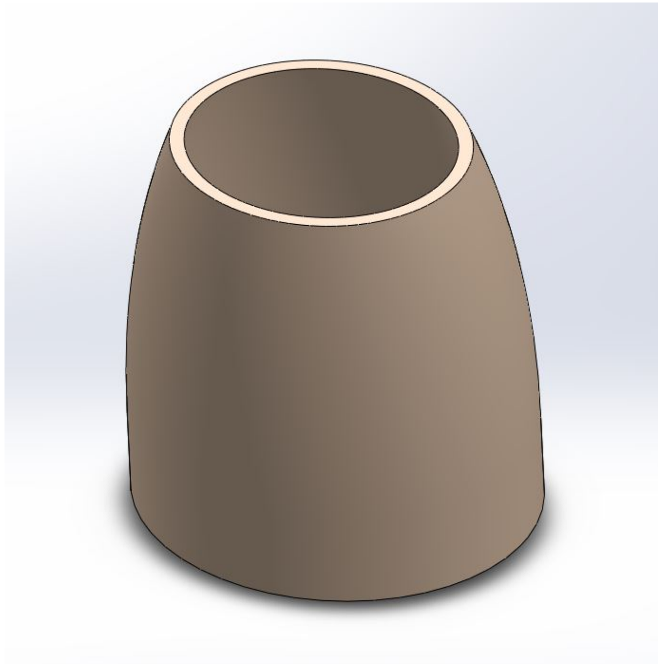


Figure 18: CAD model of skin in transverse view

Pleural cavity

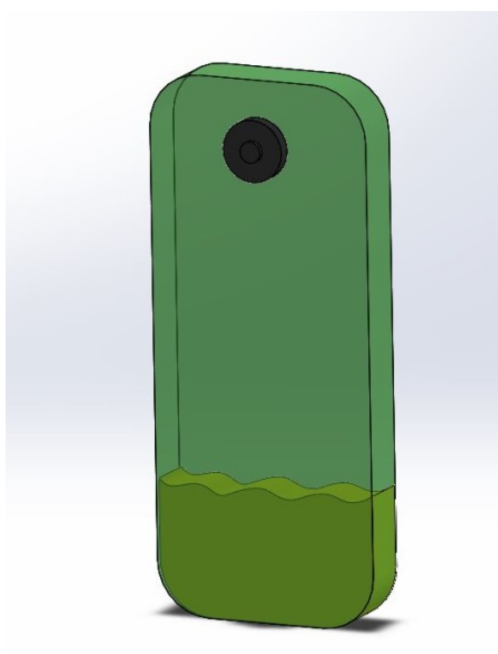


Figure 19: CAD model of pleural cavity in transverse view

Muscle and fat layer

Figure 20: CAD model of muscle and fat layers in transverse view

Completed model

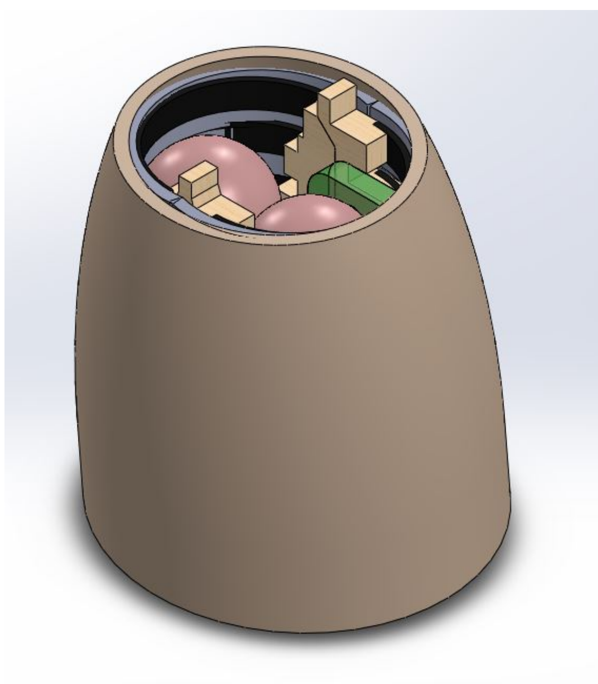


Figure 21: CAD model of proposed final design

Additional drawings and dimensional sketches can be seen in Appendix M.

Design Verification

To make the model as physiologically accurate as possible, the material chosen to create the imitation organs had to meet certain specifications as seen in Table 12 and Table 13 below. The material used to make the replica lungs had to have an elastic modulus similar to that of human lung tissue (6.6 x 10^{-6})[33]. It was also important that the needle penetration force, elastic modulus, density and durometer of the muscle and fat layer be similar to those properties as found in the muscle and fat layer of living tissue. The materials chosen to mimic skin had to have properties similar to the elastic modulus (0.0015 GPa)[33], UTS (0.272 MPa)[47] and needle penetration force (2 N)[50] of human skin. Each of these specifications was found in literature and testing was performed to find materials that closely matched the desired properties.

Table 12: Data for penetration force testing for muscle and fat layer

	Human Tissue	Neoprene	EPDM	Ballistic Gel	Foam
Needle Penetration Force (N)	35[38]	5.03 6.24 5.81	37.82 42.15 38.29	N/A	N/A

Table 13: Data for penetration force testing for skin

	Human Tissue	Ballistic Gel	Silicon Rubber	Latex
Needle Penetration Force (N)	2 [50]	N/A	2.23 2.97 3.21	3.15 2.89 3.23

To ensure the surgical simulator accurately replicates the feel of performing a Thoracentesis procedure, the materials used must match the needle penetration force of the various tissue layers. The needle penetration forces of the skin (2 N)[50] muscle/fat layer

(35 N)[38] and the pleural cavity (1 N)[50] were determined from literature. To determine which materials would most accurately mimic these forces, a set of tests were performed.

EPDM, neoprene, latex and silicone samples were collected. The EPDM and Neoprene had the same thickness of 0.5 inches. The latex and silicone layers each had a thickness of 1/16 inch.

When each material was being tested, it was wrapped around the modeled rib cage and placed on an AMTI force plate. The needle was inserted into each material and bio analysis software was used to determine the force needed to completely penetrate the material. Each time a new material was tested on the model, the force plate was zeroed. The needle penetration force was tested a total of 3 times for each material. The results from the testing can be seen in Table 12 and Table 13. The materials selected to mimic the pleural layer and cavity were too thin to be accurately tested and therefore the results were negligible and the values were determined from literature.

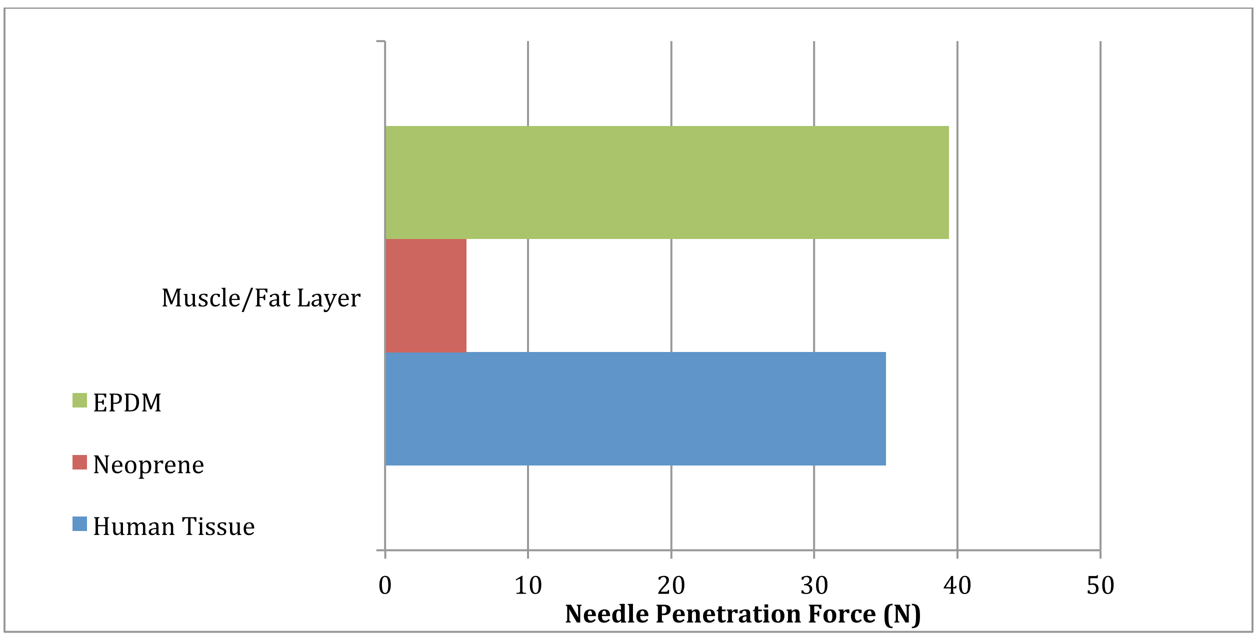


Figure 22: Graph comparing the different materials for muscle and fat layers

Figure 22 above shows the needle penetration force of the two different materials tested for the Muscle/Fat layer compared to the needle penetration force of human tissue. The bar graph takes the average measurement of both the EPDM rubber and Neoprene rubber and compares it with the actual force of muscle and fat as found in the literature.

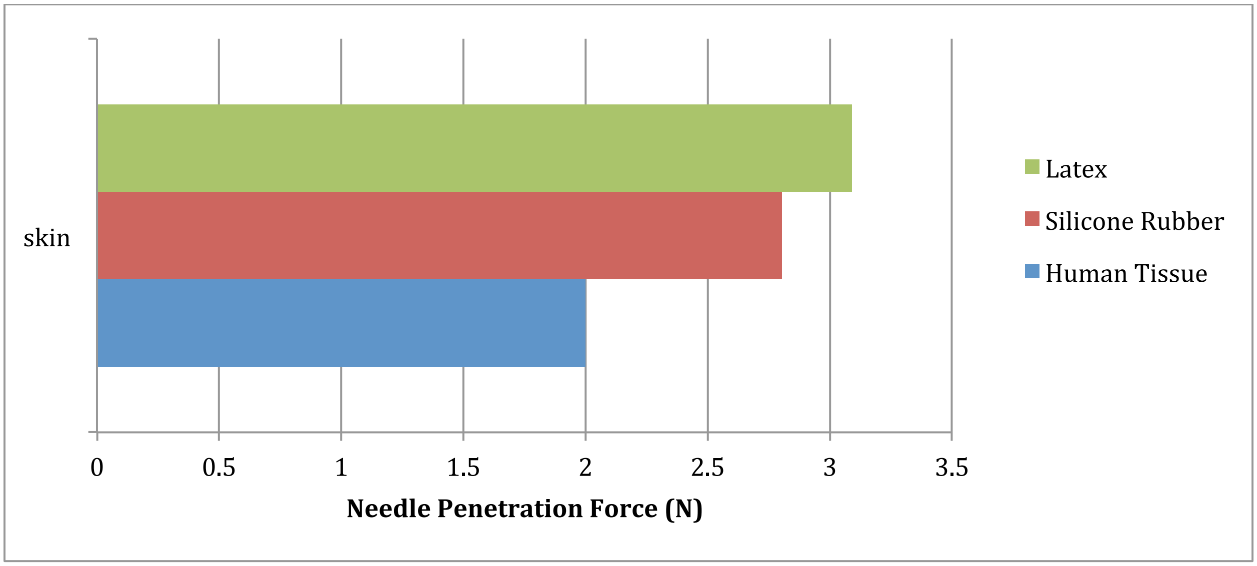


Figure 23: Graph comparing the different materials for skin

Figure 23 above shows the needle penetration force of the two different materials tested for the skin layer compared to the needle penetration force of human tissue. The bar graph takes the average measurement of both the latex and silicone rubber and compares it with the actual force of human skin as found in the literature.

Table 14: Quality testing for the model

Tests	Quality Scale	Results
Does model stand on own	Yes/No	Yes
Can x-amount of force be applied to the model without sliding	Use spring scale to measure force before sliding	
Is there leakage	Yes/No	No
Does model make different sounds when tapping out (duller sound when tapping over fluid, sharper over bone/no fluid)	1(No difference in sound) 5 (Completely different sounds)	1
Can ribs be felt	Yes/No (differentiate from just muscle layer)	Yes
Ease of needle pass through the material (latex, EPDM, shrink-wrap)	-5 to 0 to 5 (No resistance at all), (normal), (no penetration)	0
Is the pleural cavity resalable	Yes/No	Yes
Does needle leave penetration mark in latex rubber	Yes/No	No
Does the CamelBak® bag create the desired "pop"	Yes/No Potential Scale	No
Can model withstand pressure	See above	Yes
Does water drain efficiently	0-5 (Fluid does not drain), (Fluid drains properly)	4

Qualitative measurements were established to test the efficiency of the model. The parameters chosen can be seen in the left column of Table 14, and the results can be seen on the right. Each parameter was chosen to provide information about the quality of the simulator. The tests were designed to ensure the model meets the requirements that guided its design and development, works as expected and meets the needs of the clients. For the model to be considered desirable it must be able to stand on its own and not slide or tip over when pressure is being applied. The pleural cavity of the model must retain the excess fluid that is not being removed during the procedure; it is important that the bag containing the fluid is resalable so that no water leaks after the bag is penetrated. This allows for multiple uses of the bag and prevents damage and decay to the wood used in the model. The bag must also be thick enough to produce resistance so the surgeon can experience the "popping" sensation that occurs when the needle is passed through the pleural layer. One advanced feature we would like to incorporate in the model is the ability for a doctor to tap out the back and be able to hear the different sounds when tapping over fluid, bone and air. This would be an excellent addition to have, as it would provide the user with the knowledge of how much fluid has accumulated in the pleural cavity and as a result it will tell them the exact location to insert the needle. The ribs must also be able to be felt through the layers of tissue so that the surgeon can place the needle in the correct location. As aforementioned, it is important to have the chosen materials mimic the feel of inserting a needle into a real human tissue so the surgeons are prepared when it comes to performing the operation on a patient.

Table 15: Fluid drainage rate test

Number of Rubber Cement Layers	Time (s) to stop leaking
1	45 seconds
2	45 seconds
3	32 seconds
4	24 seconds
5	11 seconds
6	4 seconds

One of the main objectives of the model was to allow for proper drainage of the fluid and subsequent resealability. In order to measure such data, the fluid bag was coated with different number of layers and dried for six hours as shown in Table 15. After drying, the bag was filled with water and penetrated with a Thoracentesis needle and the length of time it took for the leaking to stop was measured. With the aforementioned experimental results, the team was able to discuss the various values in the light of each component.

Discussion

In order for the surgical model to be considered successful, results must be evaluated against various criteria. The testing and the functionality of each of the parts of the model were outlined along with comparisons to pre-existing devices. The Thoracentesis model was also created with some assumptions regarding the procedure and the anatomy and also includes certain limitations that might not be critical to success, however. Furthermore, the model also carries various implications in term of economy, environment, society, politics, and ethics. Lastly, for the completion of the model, it must be sustainable and easily manufactured in order to be mass-produced as an effective medical device.

Ribcage

Testing and function

The main focus of the replication of the ribs was to create a ribcage that would mimic the properties of the bone tissue and allow for support of the model. The model ribs had to be similar in terms of mechanical and physical properties to the human ribcage, as defined in the background. Through axial stress and strain testing physical verification, we were able to create a set of ribs and sternum that functionally replaced the human ribcage. Results of the experiments demonstrated the similarity and visual and manual inspection confirmed the expectations. The use of inexpensive and readily available materials also made the ribs and the sternum model an appropriate replacement for bone tissue and the ribcage.

Since the part of the model was also made from modified PVC for the ribs and wood for the sternum, it was also inexpensive. The team decided to use PVC because in previous literature it had shown success in representing the bone. Additionally, it was also obtained easily from the manufacturer. The main issue with the ribcage was that it was unable to provide access to the internal organs and it was not representative of the true human ribcage. The use of wood dowels and stainless steel screws to affix the ribs provided proper movement and separation of the two halves, longitudinally. In turn, this allowed access to the internal organs for replacement and fixation. Additionally, the client also confirmed the accuracy of the ribs through her knowledge of medicine and surgical procedures. Lastly, the ribcage also provided landmark separation for the medical students to determine the site of entry. By replicating the toughness and the material properties of the bone, PVC was an excellent substitute in the Thoracentesis model.

Comparison to pre-existing device

The part of the model representing the ribs can be compared to the current models that are described in the background; TraumaMan® System and SynDaver™ Synthetic Human. Although the materials used in the previous models more closely represent the bone, the team decided to focus on the cost and simplicity of the ribcage, while also aiming for a more physiologically accurate depiction. The ribs in the aforementioned models are made of a similar plastic material that is more expensive. However, upon testing, it was demonstrated that the PVC plastic is just as effective at a lower cost. The low cost makes it a more desirable product for surgeons and medical students.

The other unique feature about the ribcage is that it can be separated into two halves, which is not the case with either of the previous models. Additionally, the ribs themselves are about to be removed rather than being molded. The ribcage from the previous model is molded from a plastic cast, which increases labor and cost required while also making the process difficult. The ribs in model developed are cut individually and are attached to the sternum using screws. This eliminates the need for a mold or an expensive and time-consuming procedure. The uniqueness of the ribcage model is its simplicity, and through this, we feel that the ribcage developed is an accurate representation of the human ribcage.

Assumptions

In order to simplify the problem adhere to the specifications set forth by the clients, few assumptions were made. Primarily, the ribs were assumed to be hard and impenetrable and therefore the choice of PVC was optimal. The reason being was that they were used as one of the landmarks to pinpoint the position of the fluid. Secondly, the thickness of the ribs was thought to be insignificant in the model's objective because the procedure is carried out between the ribs and not through them. Lastly, one of the major assumptions that influenced the design was that the ribs did not curve downward from the back to the front. Meaning that all the ribs are placed on one axis and not at an angle, as is the case with the human ribs. The assumption was important because it simplified the design creation greatly by eliminating the need for a curved mold and permitted the removal of ribs. Additionally, the assumption also gave the ribcage a more rigid structure as the ribs could be attached to the front and the back. However, there are certain techniques that could be used to overcome such assumptions, such as better molding of the ribcage, which would allow for a more desirable model. Nevertheless, the said assumptions did not hinder the model from completing the objective, as it was still able to provide support and physiological accuracy.

Limitations

As is the case with any design, there are certain limitations that cannot be overcome with the current objectives. One of the major limitations that altered the interpretation of data was the choice of material. There are only certain materials within the budget that would be easily manufactured and could act as a human ribcage. PVC was chosen due to its availability and low cost. Moreover, it also does not create a problem in performing the procedure. The same is the case with using wood for the sternum and the back plate. Since these parts of the thorax are not necessary in the procedure itself, they are simply used as a placeholder for the ribs. As long as the physiological dimensions are accurate, the type of material used is not critical to the success. Since the ribcage is one of the simpler parts of the model, besides the cost and the time constraint, there were no significant limitations established.

Muscle, Fat, and Pleura

Testing and function

One of the major objectives of the Thoracentesis model was to replicate the human tissue including the muscle, fat, and the pleural lining inside the ribs. Nevertheless, in creating such tissue, several materials were examined. In order to choose the best materials for each of the components, together or separate, experimental analysis needed to be done. In such projects, one of the major points of analysis was physical inspection. Through brainstorming, the team decided to use neoprene rubber and EPDM as the top candidates. In order to expedite the process and creation, the three layers were combined because the major objective of this part of the model was to provide pressure similar to muscle and adipose tissue. After penetration, there is no pressure in the pleural cavity and therefore, combining the materials was the best option.

As described in the experimental section, the determination of the final material was accomplished through physical and force testing. Physical analysis of the materials showed that the EPDM rubber had a similar feel to the human tissue when compared to a cadaver. Additionally, force testing on the material using a Thoracentesis needle displayed that EPDM provided the closest resistance to the tissue layers in the body. Nevertheless, one of the major concerns was the collapse of the catheter during the drainage of fluid. The client, Dr. Heitmann performed the procedure and affirmed that the catheter did indeed stay intact and fluid could be drained. The major objective of the tissue layer was to provide a physiologically accurate model for insertion of the needle and allow for proper drainage, and the EPDM layer accomplished the task.

Comparison to pre-existing device

In order to compare the tissue layer component of the design to the previous designs by TraumaMan® and SynDaver Labs™, several aspects must be measured. One of the major differences is the layer of tissue represented in the previous models, when compared to the model created. In TraumaMan®, there is only one layer of latex to represent the fat, tissue, and the skin layer. Additionally, there is no way to represent the pleural lining as well. On the contrary, SynDaver Labs™ has created a human model that contains muscle, adipose tissue, and the pleural lining. However, the model is very expensive and medical schools are unable to afford such high prices. When compared to these models, the layers in the presented models are representative of the three layers mentioned. Additionally, the thickness measured in the layers is also similar to the thickness of the thoracic cavity of an average human being.

Additionally, during testing, the EPDM rubber came very close to representing the pressure produced by the human tissue. When compared to TraumaMan®, which lacked any sort of muscle layer, and SynDaver Labs™, which uses unique tissue that are very expensive, the model created is very efficient. Furthermore, the EPDM rubber fulfills the objectives of the design problem as well. The difference in the experimental data is due to the lack of expensive materials that represent the three layers more closely than the rubber. The data analysis is the same for all three models; as using objective and quantitative reasoning, the tissue layer created by the team completes the necessary objectives.

Assumptions

In order to simplify the layering of the tissues, some important assumptions were made. Primarily, the muscle, fat, and pleural layers were assumed to be one single layer as opposed to three different layers. By combining the three layers, the cost and the production were much more simplified. Using EPDM rubber to represent the three layers allowed the model to contain fewer components. Although this is not physiologically accurate, one thick layer provided the necessary pressure for the procedure. Additionally, combining of the three layers lowered the cost because there was no need for other materials. Lastly, it also created a tissue layer that could be attached easily to the ribs without using several different adhesive devices. In this case, only Velcro® was used to attach the EPDM to the ribs. However, choosing three different layers can eliminate the aforementioned assumption, as it would be the client's choice on whether to focus on physiological accuracy or procedural accuracy.

Another assumption made for the tissue layers was the lack of blood vessels and space between the tissues themselves. In order to make the model simpler and adhere to the requirements of the problem, the need of elaborate blood vessels was eliminated. Furthermore, the procedure rarely requires the use of an incision, and therefore the presence of blood seems insignificant compared to the other components. In short, by combining the three layers into one, the team was able to create a cheap and efficient tissue layer that simplified the procedure as the data showed that it was representative of the human tissue.

Limitations

Our tissue component selection was made due to time and budget limitations. Instead of selecting individual material layers that mimic the material properties of the muscle, fat, and the pleural layers, we combined the three materials into one at a reduced cost. Additionally, the combination did not cause any problems in terms of the accuracy and the force values of the layers. Another limitation was the lack of spacious cells in the EPDM. Since the normal muscle layer has nerve cells, a local anesthetic, lidocaine, is administrated to decrease the pain during the procedure. However, the EPDM does not contain any space for the lidocaine to be dispersed. Therefore, EPDM limits the use of lidocaine and requires a dry needle to be used. Furthermore, the sense of lack of pressure after the needle has penetrated was also considered a limitation because it prevented us from using materials that more accurately represented the muscle but did not provide the "pop" that is felt when the needle has completely penetrated through the layers. As always, the team decided that the procedural accuracy was more important than aesthetics since the focus group includes medical students. Nevertheless, this is not critical to the success of the procedure, because the main objective is the drainage of fluid and providing enough pressure to resist the penetration of the needle. The project deals the core of the procedure itself, not the pre-procedural steps. As always, time was also a limitation as it prevented the team from exploring different options regarding the material, such as fusing of three different layers.

Skin

Testing and function

Similar to the other layers, the skin also had to replicate the properties of the human skin. Similar force testing and physical testing was performed on various layers as well in order to determine the best option. The main concern was the thickness and the feel of the material. The team decided to use latex rubber as the final material to represent the skin in the model due to its various similarities to human skin. In literature, it has also been used to represent the outer layer due to its toughness and tensile strength. Through testing and obtaining industry values for the material, the durometer or the toughness of the latex was closer to the skin than any other material.

Another concern was to make the skin penetrable and accessible. By using Velcro® and testing with a needle, the team was able to accomplish the task. It was also readily available from the manufacturer. Therefore, latex rubber was sought as the best option for the skin layer due to its various similarities in properties, and affirmation from reputable sources such as the manufacturer, literature, and Dr. Heitmann as well. Lastly, the main objective was to provide an outer layer similar to human skin and the material chose accomplished the task, while also preventing the use of several unique layers.

Comparison to pre-existing device

The pre-existing devices that compare to the skin layer created in the Thoracentesis model are TraumaMan® and SynDaver Labs™. The major difference between the three models was the choice of material. As previously explained, TraumaMan® only has one layer to represent all tissue and it closely resembles the skin. Moreover, the human model created by SynDaver Labs™ contains a realistically textured skin with multiple discreet layers. The skin has a mean force of approximately 2-4N with the penetration test, which is very close to the value of the force in human skin, depending on the part of the body.[27]Therefore, the model is able to mimic the skin properties very well. However, it is also currently very expensive and unaffordable. Therefore, the use of latex rubber seemed like the closest contender. The penetration force measured was approximately 2.8N and it also mimicked the skin physically. By using a cheaper yet still accurate material; the team was able to cut down on the costs and the production.

Although the design performance of the latex is lower than the ones used in TraumaMan® or SynDaver Labs™, it is close enough to complete the objective and provide the necessary resistance and feel. The penetration force is regarded as the amount of force needed to insert the needle through the material. Since the value was close to the value of the skin (2-4N), it can be concluded that latex rubber was an optimum choice. The differences occur in the tensile modulus values (4.5×10^{-5}GPa vs. 5.0×10^{-4}GPa), and the reason being is that the latex rubber is one solid layer of material as opposed to several thin layers of skin. Nevertheless, the differences are not critical as latex is able to mimic the skin accurately, given the limitations.

Assumptions

By making assumptions, the creation and the manufacturing of the skin layer was simplified. One of the major assumptions made was that the skin is one single layer of material as opposed to several dermal layers in the human body. The reason being is that it allowed the team to use one material as a substitute and lower the cost and manufacturing time. The assumption also did not hinder the model from completing the objective as the single layer of latex still replicated the properties of the skin. It influenced the interpretation of data because the mechanical test values were much higher, due to the difference in one layer versus several thin layers.

Another assumption was that the skin is not self-repairable and contains a smooth, non-wear material. Since the penetration marks made my the needles are insignificant, this assumption is unable to substantially influence the data. Since the latex is unable to reseal on its own and does not wear like the skin, the assumption needed to be made in order to achieve the objective. However, using a more realistic yet expensive material and attaching it to the model using Velcro® can overcome the assumptions. Nevertheless, the decision would be up to the client's choice of material needed.

Limitations

In creating the skin layer and researching the ideal material that should be used, there were certain limitations that needed to be established. One of the major limitations was the lack of surgical knowledge. The reason being is that without proper knowledge, the team was unable to accurately determine if the material was indeed the correct one from a medical standpoint. However, we were able to consult Dr. Heitmann for advice regarding the material. Additionally, the skin layer is only used as a penetrable surface to mimic the real skin and the latex was the ideal material. Therefore, the physical aesthetics of the layer were insignificant compared to the mechanical properties. As always cost and time constraints were also a concern because they prevented us from using more expensive materials such as the ones used by SynDaver Labs™. Additionally the lack of manufacturing capabilities prohibited us from creating our own material polymer for use as skin.

Although there were certain limitations associated with the layer, the final material choice aided in the completion of the model. The similarities in penetration force and tensile modulus showed that latex was indeed a good choice. Furthermore, by reducing the manufacturing costs and time, the team was able to create a skin layer that accurately depicted the physiological properties of the human skin.

Lungs

Testing and function

Although lungs are not the primary objective of the model due to the procedural requirements, they are necessary in creating a complete and physiologically accurate thoracic cavity model. The major reason for the presence of lungs is if they are punctured, it could create problems for the patient. Therefore, the main test was to be able puncture the lungs and create a set of lungs using proper materials. The speed bag bladders that are made of latex rubber are self-sealing to an extent to prevent the release of air and also provide the ideal size for the lungs in the model. The major experimentation for the lungs was to penetrate them using a needle, which was successful. Additionally, the use of a stopcock attached to a needle that is inserted in the bladder allowed for a permanent access to airflow within the lungs. Compressing the lungs and opening the three-way stopcock could release air. Similarly, by inserting the needle into the stopcock and using a bike pump could provide more air into the lungs. Therefore, the bladders were able to act like lungs and be filled with air. In the end, they were able to meet the objectives by having similar properties to the lung tissue and also release air upon accidental penetration.

Comparison to pre-existing device

As with all of the other parts of the model, there is variability between the speed bag bladder lungs and the lungs produced by two current companies, TraumaMan® and SynDaver Labs™. The lungs contained in the first model are made of a similar silicone rubber material in a smooth and curved brick shape with a hand pump attached for inflation and deflation. In the model by SynDaver Labs™, the expensive lungs are made of the most realistic synthetic material made to mimic the human lung. The key difference in our model is the cost-benefit using a material that works just as well.

The major alteration made on the model was the choice of material, as we used latex speed bag bladders. Additionally, the puncture test and the inflation and deflation results demonstrated that the bags are able to functionally represent the lungs. The team did not decide to do extensive testing on the lungs because they were secondary to the other parts of the model. Therefore, by performing the major tests outlined above, we were able to deduce the proper material to model as lungs. Additionally, the lungs are also smaller than the ones produced by other companies because of the size of the thoracic cavity itself. However, this does not prevent us from completing the objectives of the procedure itself. In short, the speed bag bladders are the ideal choice given the cost and lack of expertise in the field.

Assumptions

Since the lung is a complicated organ with various physiological functions, the team decided to imply several assumptions in order to simplify the process. The reason being is that they are a secondary part of the model because they are not necessarily required during the procedure.

One of the assumptions made was that the lungs in the model did not have a pleural lining or a breathing mechanism for automatic inflation and deflation. This means that the lungs were inflated to a certain volume and air was only removed when required. The absence of the thin pleural lining did not hinder the success of the project due to its unimportance in the procedure. Eliminating the breathing may be physiologically inaccurate, but it allowed the team to simplify the material choice and provided easier interpretation of data. Nevertheless, it did not take away from the procedure itself because if there if fluid in the pleural cavity, the lungs are unable to inflate or deflate in the patient.

Another assumption made was the shape and the dimensions of the lungs. Since the speed bag bladders were the best choice in terms of material, the team had no ability to choose the shape of the bladders. Therefore the lungs are confined to the almond shape only with no lobes. The human lungs also have three and two lobes respectively; however, the team felt that there was no need for lobes because penetration in lungs is the same throughout. The shape did not make a difference either in the lens of the procedure because the needle could penetrate the material regardless. Therefore, by eliminating the need for lobes and the exact shape of the lungs, we were able to minimize cost and prevent the requirement of more exquisite and labor-intensive materials. However, in order to eliminate the assumption, a better shape may be chosen, which will allow for better physiological accuracy.

Limitations

In order to create the ideal lung using an affordable but physiologically accurate material, the team accounted for certain limitations. Of the major constraints was the material choice. Since the lungs are highly stretchable, we had to choose a material with high elasticity. Therefore, we were restricted to using latex materials as the best choice. Additionally, the size and shape of the lungs were also limited. Since the model is very compact, the bladders had to be smaller in size when compared to the average lung. Moreover, the shape was also not accurate due to limitations in material choice. However, these aspects did not come in the way of the procedure, as accidental penetration of the lungs was still possible. Since the model only focuses on the Thoracentesis, the physiological accuracy of the lungs is unimportant.

Pleural Cavity and Fluid

Testing and function

The major objective of the Thoracentesis model is to allow the drainage of fluid from the pleural cavity using a needle. In order to tackle this problem, the team decided to use a bag to represent the pleural cavity. The bags are self-sealing at the top and are coated with rubber cement to allow for resealing after needle penetration. The fluid contained in the bags is water mixed with food coloring to provide the discoloration. The major experimental procedure should be to penetrate the bag with the needle and perform the procedure. The problem of draining the fluid could be solved using the bags because they permit drainage of fluid from the cavity.

Further testing includes time tests and penetration tests to analyze the time it takes for the bags to reseal after penetration and the fluid to stop flowing. The time tests also confirmed that using the bags with the rubber cement coating is an ideal choice because the bags resealed only after a few seconds, which is within the normal range. In addition, penetration tests also demonstrate the force it takes to get the needle through the first layer, which represent he pleural lining in our case. The values were similar as shown in the results section, further confirming the accuracy of the fluid bags. In conclusion, the bags were able to provide a container for the fluid in the model and also successfully complied with the requirements of the procedure, as confirmed by the client as well.

Comparison to pre-existing device

Although TraumaMan® and SynDaver Labs™ models are quality devices, due to their design and construction, they lack a fluid containing pleural cavity. In TraumaMan® there is no pleural cavity or a bag to hold the fluid, and therefore the model is unable to accommodate the drainage of the fluid. Conversely, the model created by SynDaver Labs™ has complete pleural lining and pleural cavity without fluid containing bags and is very expensive. Therefore, the team decided on using bags as the pleural cavity to easily contain the fluid. Although the structure of the thoracic cavity model did not allow for an open space for the fluid due to risk of leakage, the bags performed very well as replacements. The unique feature of the model is that it truly allows the drainage of fluid without the problem of leakage. Additionally, the bag is also self-sealing which has been a problem with previous models. The resealing rate is within the optimum range and the penetration force is similar to the pleural lining, as outlined in the results. The differences arise in the material choices and the choice between bags or an empty cavity, and we feel that using a self-sealing bag with a unique rubber coating provides the best option for a pleural cavity, while preserving the cost.

Assumptions

In order to simplify the model, the team made several assumptions regarding the pleural cavity. Primarily, it was more beneficial to use a bag to contain the fluid rather than an open cavity due to the dimensions of the model and lack of closure. Therefore, we assumed that the pleural cavity is a bag that contains the fluid in the bottom half of the bag. The reason for the assumption is that it allows for moving the fluid to any part of the cavity and performing the procedure. it is also different in interpreting the data because we could measure the properties of the coated bag and have quantitative data along with the success of the procedure itself.

Additionally, the model assumes that there is no real pleural space and the layers of the bag constitute the pleural lining. This changes the lens through which the data can be interpreted because it requires us to obtain data on a container as opposed to a cavity. In order to clear these assumptions, further analysis of the model design is required, along with using materials that may contain the fluid themselves without the need of a container.

Limitations

There are certain boundaries that must be drawn in order to accomplish the objective of drawing fluid from a cavity. For example, the team was limited to using a bag as the pleural cavity because the model did not allow for a space containing fluid. Since the model was made out of wood partly and it would be unreasonable to fill the entire bottom of the model with fluid, it was more beneficial to use a bag to represent the pleural cavity. Additionally, due to physiological constraints, the bags were only allowed to have a certain thickness. As the pleural lining is only 0.15 mm thick, it would be physiologically accurate to use a thinner material.

Although there were limitations in creating the pleural cavity, the container allows the medical trainees to target the specific area. Additionally, since fluid is only required at the bottom of the lungs, filling the entire model is irrational. The container layers can also act as the pleural lining making the bag a suitable option for performing Thoracentesis and draining the fluid.

Economic Impact

As it is noted, the current models in the market are very expensive, ranging from $5000-$25,000. One of the goals of the project is to create a model that is affordable, for medical schools, surgeons, and even medical students. By using commonly found materials and techniques, we were able to create a model that could be design with ease and as fewer manufacturing steps as possible. This allows the medical schools to spend less money on models that are functionally as efficient when compared to more expensive counterparts.

The ribs are made of PVC and wood, while the lungs are created using speed bag bladders. Furthermore, the tissue layers are made of EPDM rubber and latex, which can be commonly obtained as well at a reasonable cost. By affirming certain assumptions, the model was simplified to using the cheaper products. By eliminating the need for high-tech designs and physiologically perfect models containing breathing lungs and beating hearts, expenses were reduced. In summary, the model was able to accommodate the need to perform Thoracentesis repetitively, while also considering more economical options for the parts.

Environmental Impact

Since the model created is used for medical purposes, it can carry several environmental impacts. In terms of positive impact, the model is created out of readily available and degraded materials, which means that the model would not cause harm to the environment. Currently, models have been created that are not highly sustainable due to their large footprint or materials used. The model created in the project has a relatively smaller footprint as materials such as PVC, wood, EPDM, and latex outlined the design. By using such materials, we are able to reduce the negative impact of the model on the environment. Since it is easily disassembled and reassembled without any harm, it is also a better option. The decrease in unique materials will allow the surgeons and medical schools to obtain them easily, preventing the creation of man-made materials. Furthermore, this eases the manufacturing process, which in turn reduces the harm done on the environment. We believe that through the use of readily available and eco-friendly materials, we have created a model with minimal negative effect on the environment.

Societal Influence

The surgical model will have few influences on the society once it is produced and introduced to the market. Primarily, since the model is a simplified version of the previous model, yet it still completes the task, it will attract medical students throughout. Medical schools will be attracted to the model and will be willing to purchase it in bulk quantities due to its ease of manufacturing and lower costs. Additionally, the model will also appeal to the general audience because they will understand the different physiological parts to the model as well and will be able to train with it. As consumers, the model will not only aid surgeons, but also EMTs and medical students, who will be able to purchase or create their own version of the model due to its simplicity. As always, the goal of the team will remain the same, providing a functional surgical model for Thoracentesis, while being marketable to a vast audience.

Political Ramifications

Although the surgical model does not seem to have any political ramifications when compared to current research hot topics, it still would cause certain influences on the global market and culture. Primarily, it would alter the market for surgical training models due to it being inexpensive. Therefore, the model will be able to be marketed to all parts of the world, even countries that may be unable to afford other, more expensive technology. In order to practice the procedure, several markets around the globe are trying to create a physiological accurate model while minimizing cost and effects. Furthermore, it will also please ethical groups advocating human and animal rights, as the surgical model will seeks to reduce the use of cadavers and animal models.

The International Society for Human Rights (ISHR) and People for Ethical Treatment of Animals (PETA) will seek to promote the product as it eliminates the mistreatment and political dilemma associated with cadavers and animal experimentation. Additionally, the overall neutrality of the model allows it to be culturally accepted throughout the world without any consequences. The goal of the project is to eliminate the use of expensive surgical models, humans, and animals for Thoracentesis training, and the model accomplishes the task.

Ethical Concerns

The Thoracentesis surgical model is created to affect and improve the lives of patients and doctors alike. Since the surgeons and medical students will be able to train for the emergency procedure Thoracentesis repeatedly, they will be better educated in shorter period of time. As a result, there would be a higher chance of patients to survive and success of the procedure. Additionally, practice will prevent severe pain, as the surgeons will be proficient in the procedure. For the lives of medical professionals, the model can be easily manufactured and is inexpensive, and therefore will provide comfort and ease of training to the professionals. Without the need for expensive manufacturing processes and materials, they will be able to focus on the medicine and the procedure itself. Increasing the success rate of the procedure and limiting the need for human and animal models will provide medical professionals and patients with an enhanced quality of life.

Health and safety

As is the case with any biomedical project, health and safety of the consumer is one of the most important factors. The team decided to make it a goal of the project to create a model that is safe and does not cause harm to the user or other clients. Although Thoracentesis is one of the emergency procedures, it can be simplified in a few steps.

By creating a model with enclosure and no harmful chemicals or materials, we were able to ensure the safety of the user. Since medical students are already trained to be sterilized and safe, the model is able to implement such precautionary measures by being partly sterilizable as well. Moreover, the materials used have not caused any catastrophic failure that may injure the user as it prepares the professionals to be more trained when operating on a patient. A step-by-step procedure outline will also be provided in order to ensure proper safety techniques are employed. With any medical procedure, including Thoracentesis, there is an issue of health and safety regarding the use of needles and medical equipment. However, the team believes that the medical users will be knowledgeable and supervised by a superior and along with the protocol outlined above; the model will be safe to use.

Manufacturability

One of the primary goals of the project was to provide simplified manufacturing of the product while also accomplishing the task. As noted above, the model is created with easily obtainable materials. For example, the ribs can be created using an electric handsaw and the layers can be cut using scissors as well. All of the other materials are pre-made and can be obtained with ease. The toughest part of the manufacturing process would be the attachment of the ribs to the sternum and the back plate. However, the team has designed the model in such a way that it can be disassembled and reused several times. By minimalizing the use of expensive and time consuming procedures and materials, we were able to achieve high productivity. Using not only physiologically accurate and functional materials, but also designing the model in a unique way, optimum manufacturability could be achieved. A detailed outline of the manufacturing process can be found in Appendix I.

Sustainability

The Thoracentesis surgical model is an excellent example if a functional yet sustainable product due to its various features. Primarily, since it is made from materials that are easily obtained or naturally occurring, it is able to prevent high-cost and energy release. Furthermore, the manufacturing process and the model itself does not use any form of non-renewable energy. Since only electricity was used to manufacture the various parts of the model, it is energy efficient as well. The materials chosen are also known to last a long time and therefore will provide proper training to the medical professionals repeatedly. Likewise, the simplification of the procedure will also allow the medical professionals to perfect the major steps without compromising the details. Lastly, the model was created to relieve the increasing cost of such surgical models present in the market. By creating a self-sufficient, resealable, cost-efficient, and easily manufactured design, we were able to improve one of the major lacking aspects of the current models, sustainability.

Final Design and Validation

After performing various different experiments and needs analysis, the team devised a final list of materials used to represent each of the components of the thoracic cavity, in the final model. The list of materials established through the engineering approach is provided in Table 16 below:

Table 16: Final list of materials

Component	Material Used
Skin	Latex Layer (5/32 in.)
Muscle/Fat	EPDM Rubber
Ribs	PVC
Lungs	Speed Bag Bladder
Pleural Lining	IV bag
Fluid in Pleural Cavity	Colored Water

Sternum Design and Fabrication

A template of the sternum was first drawn. It was designed to imitate the size and shape of the sternum and connective tissue of an average male as mentioned in previous chapters. The template was then traced onto a piece of plywood 5/8”thick. Using a band saw, the sternum was cut out in two parts so that the model could be taken apart in case any internal pieces needed to be removed or fixed. The rough edges were sanded until smooth. Notches were placed in the outer front edges of the design to allow for the connection of each rib. Using the drill press and a #38 twist drill bit, 2 holes were drilled on each of the edges to allow for the connection of the ribs. Holes were also drilled on the inside of each piece to allow for a dowel-connection system between the two halves of the sternum.

Vertebrae Design and Fabrication

A template of the backbone was created to replicate the size and shape of the backbone and connective tissue of an average male. The template was then traced onto a piece of plywood 5/8"thick. Using a band saw, the backbone was cut out in two pieces. The rough edges were sanded until smooth. Notches were placed in the outer front edges of the design to allow for the connection of each rib. Using the drill press and a #38 twist drill bit, 2 holes were drilled on each of the edges to allow for the connection of the ribs. Holes were also drilled on the inside of each piece to allow for a dowel-connection system between the two halves of the Vertebrae.

Rib Design and Fabrication

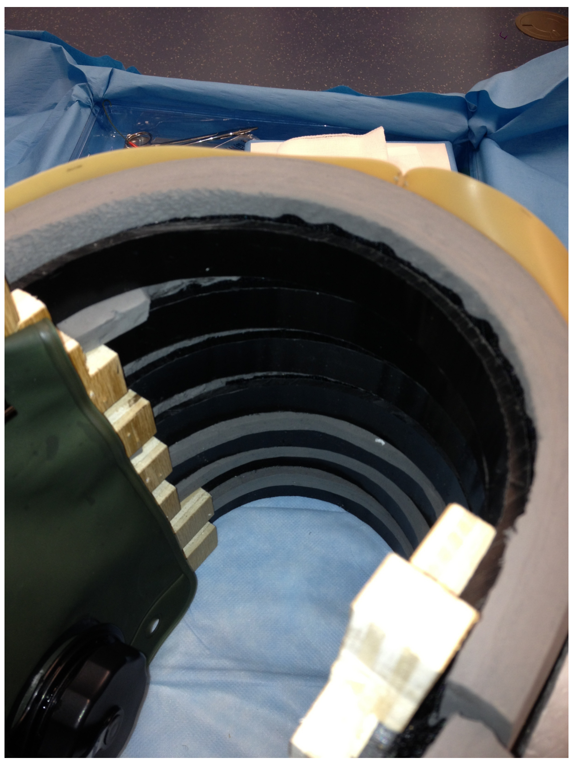


Figure 24: Final ribcage component

Each rib was cut out of a tube of PVC pipe with an outer diameter of 6 inches as illustrated in Figure 24. The PVC is shown in black surrounded by the other layers. A drop saw was used to cut the tube into rings of 2 cm thickness. A band saw was used to remove part of each ring until the length of each ring was 7 ½”. Using a drill press and a 1/8” twist bit we then made two holes on each end of every rib. These holes were used to screw the ribs to both the sternum and back plates.

Sternum, Vertebrae, and Rib Assembly

Dowels connected each half of both the sternum and vertebrae to each other. A dowel of 1/8” diameter was cut into 3, 1”pieces. These pieces were glued into the pre-drilled holes on one side of both the sternum and back plate. The other half of the sternum and back plate were connected respectively. Each rib was then screwed in to its corresponding place on both the sternum and back plate.

Muscle and fat layer design and fabrication

Figure 25: Image of various tissue layers of the final model

EPDM Rubber with a thickness of 0.5 inches was intended for the design of the muscle and fat layer. However, we received material with a thickness of 1”. Because the wrong thickness was purchased, we had to create a frame for the material to cut the thickness in half. The frame was created using scraps of plywood. The base of the frame was 22 1/2 “by 14 ½”. 2 rods of ½”plywood were cut to 22 ½”and screwed to their respective sides of the base. 2 rods of ½”plywood were cut to 14 ½”and screwed to their respective sides of the base. A rectangular piece of EPDM 22“x 14/1/2”was cut out of a sheet of EPDM rubber using a utility knife. This sheet of rubber was then placed securely into the frame created as depicted in Figure 25. The layers can be peeled back and reattached as well. A rope saw was used to slice the thickness of the EPDM rubber in half. Seven slices were then cut into each end of the rubber to allow for a tight fit around the ribcage. Each flap was tightly wrapped around the base of the model. Once the two flaps met each other in the front, the excess material was removed. This was performed for both sides of each rib.

Muscle and fat layer assembly

The muscle and fat layer were attached to the ribs, sternum and back plate via Velcro®.

Skin design and fabrication

A 22 ½”by 14 ½” sheet of latex rubber was wrapped around the model. Because the base of the model is larger than the top, the material had to be tailored. This was hand sewn using needle and thread.

Skin assembly

Figure 26: Final skin assembled on the model

The skin was made to fit around the model with a slight overlap so that it could be attached via Velcro® for easy removal as shown in Figure 26. The latex layer is very representative of the skin and has a larger area to encase the complete model. The skin can also be peeled back to show the different parts of the model. Foam hemispheres were also used as breasts to differentiate the front and the back of the model, to allow for easy land marking.

Lungs design and fabrication

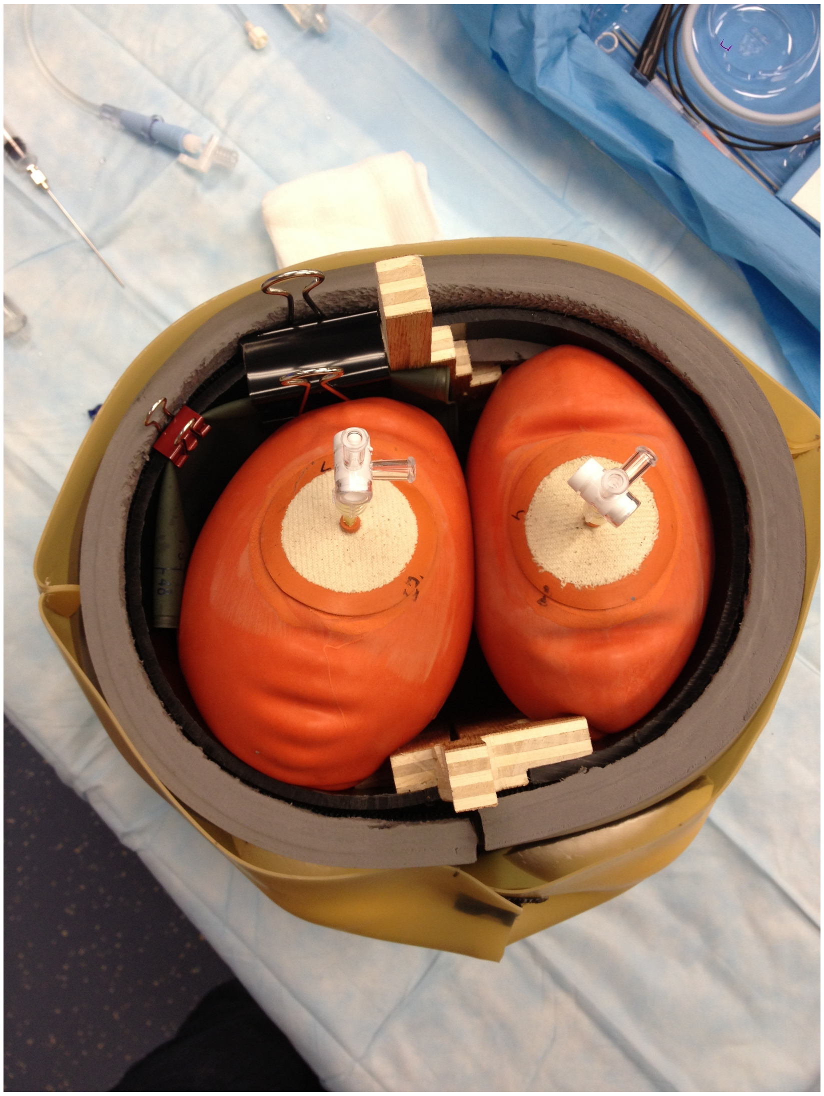


Figure 27: Image of the lungs used in final model

Because the lungs were needed as placeholders, speed bag bladders with a dimension of 9.25" L and 7" width at the center were purchased. The bladders were filled with air and placed within the thorax cavity as shown above in Figure 27. The team ensured that the bladders fit evenly and securely to mimic the true placement of lungs. The speed bag bladders are placed inside of the model and filled to their maximum capacity to secure a tight fit.

Pleural cavity design and fabrication

A CamelBak® water bladder with dimensions 16.5” L and 6.5” W was purchased for the pleural cavity and lining. It is attached to back wall of the sternum using a paperclip.

Mass production and assembly plan

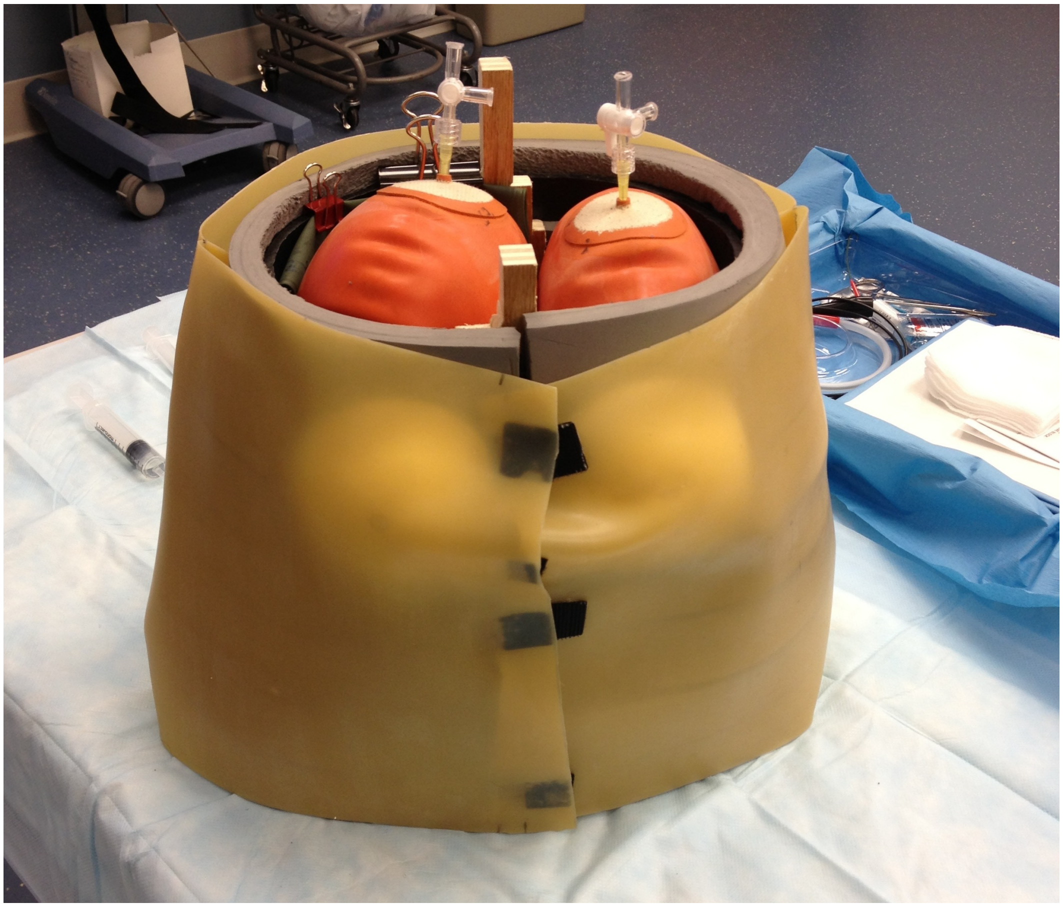


Figure 28: Final model assembled

The entire ribcage comprising of the ribs, sternum and back plate would be pre-assembled with the muscle/fat layer and skin pre attached. The lungs and pleural cavity/lining would be included; however, these items will be left for the user to attach. Figure 28 is the completed model with all of the parts assembled. The model shown above is physiologically accurate in terms of organ and tissue placement. The individual ribs would be made by injection molding PVC, into appropriate molds. This would allow us to make the simulator much more anatomically correct.

Validating the simulator's ability to evaluate surgical performance

After completing the construction of the model, various steps must be taken to validate the final model in its ability to fulfill its functions. Each of the aforementioned dimensions will aid in the validation of the engineering specifications.

Applied testing

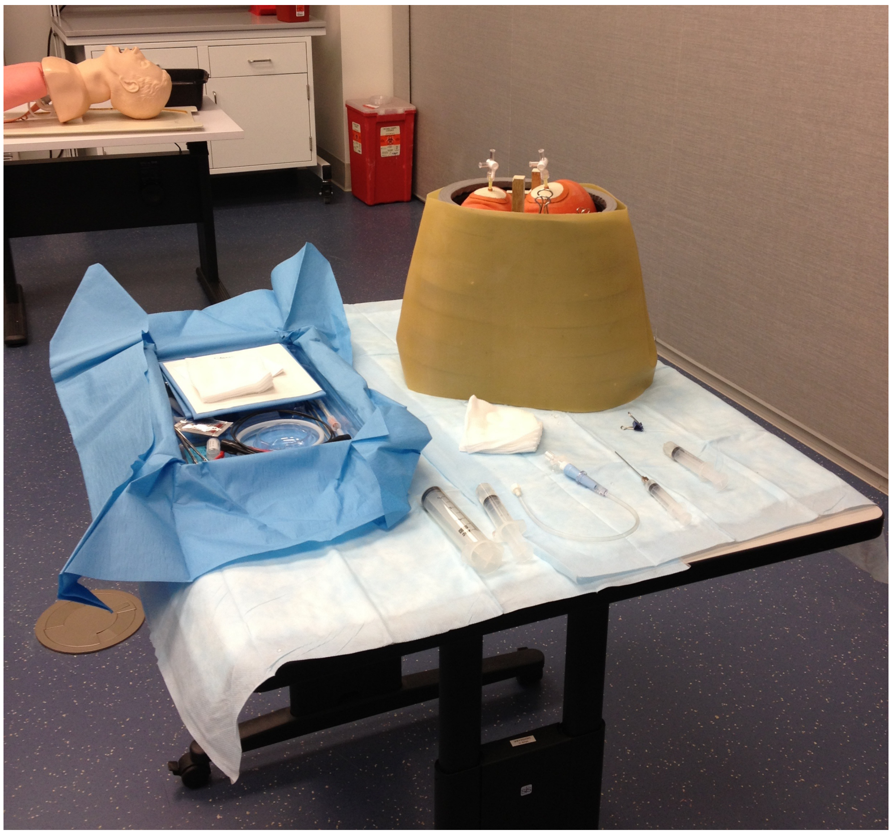


Figure 29: Testing setup of final model with Thoracentesis kit

In this validation step, the simulator will be used in an applied setting. A novice user, Melinda Taylor, was trained on the simulator, and she then performed the procedure on the model under the guidance of Dr. Heitmann. These results show how well the simulator is able to improve the performance of a student, which is a critical aspect of a simulator. Additionally, our client using the setup shown in Figure 29 performed Thoracentesis on the model. The figure shows the Thoracentesis kit with the needles used and the model next to the kit. The specific contents of the Thoracentesis Kit can also be seen in Appendix A. The procedure was performed in the Simulation center on the small operating desk as shown above. Within the surgical setting, the model was successful in demonstration the procedure in its entirety. As s result, fluid drained from the model was contained in the needle shown below in Figure 30.

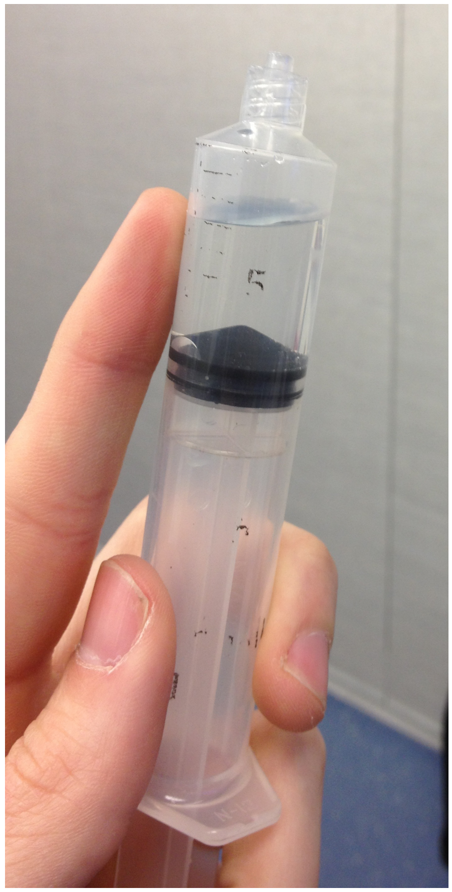


Figure 30: Proof of fluid drainage into the needle

The above figure shows that the model indeed was able to allow for fluid drainage into the needle, thus completing our main objective. Additional Images of the model and the procedure can be seen in Appendix N.

Construct validity

In this step, the simulator will be used by surgeons having a wide range of expertise and will be evaluated in its ability to differentiate between skill levels.

Conclusions and Recommendations

Project summary

The overall goal of this project was to create an inexpensive physical surgical simulator that can be used by surgical residents and interns to learn how to perform the Thoracentesis procedure. Our model was accurate in simulating needle penetration force, needle penetration distance, tissue properties, fluid accumulation volume, fluid drainage rate, and remedial surgical complications and error detection. It also can be used in a catheter-aided Thoracentesis, as the rubber we chose does not collapse the catheter. Overall, we were able to create a successful model from which an emergency surgeon was able to complete a full Thoracentesis procedure from start to finish (with the exception of lidocaine injection). In total, our model's manufacturing cost was approximately $93, which is significantly expensive than our target cost of $500.

Future improvements

Although our model was successful in a surgical simulation, there are many improvements that we would have liked to introduce, if our timeline and budget had permitted us to do so. These improvements include the following: A solid internal cavity (rather than air filled), a more thorough engineering approach involved with selection of materials, better encasement for our model, a clinical trial to ensure validation of our device as a surgical trainer, a better technique for mass production of our model, and a more resealable plural cavity.

One of our goals was to make our surgical simulator as anatomically accurate as possible. Although it was successful in a surgical trial, we feel as though we could have made bigger strides in terms of an accurate internal environment. The group experimented with ballistics gel as an encasement method for the internal organs of the model. However, it was not until late in the design phase that the group integrated a system of one-way valves and hoses as a refilling method for the pleural fluid and air in the lungs. The original design called for the removing and refilling of both the lungs and the pleural fluid.

Encasement of the internal cavity would have made it impossible to remove the necessary parts to allow for multiple uses. If time had not been such a restriction, the group would have used a gel-like material to encase the internal organs, thus making the model more anatomically accurate and eliminating the misrepresentation of the air-filled cavity incorporated in our model.

Another improvement our group would have made provided time had not been a factor would have been better encasement of the internal environment of our model. Late in the design phase after testing had been completed, the group decided to make the model more aesthetically pleasing by encasing the model so that the functioning parts could not be seen. The group had the idea of obtaining a Styrofoam® manikin bust from a wig store. This bust ended up being disproportional to the rest of the torso. The group also created a dome-shaped fixture to mount on top of the model. This ended up looking less aesthetically pleasing than the Styrofoam® bust.

Although the model was successful in a surgical trial, this did not fully satisfy the group as far as validation of the design. The design was intended to teach the proper protocol and methods to performing an effective Thoracentesis procedure. During testing, the procedure was performed by an experienced professional. Had the team had more of a variety of resources, we would have set up trials for medical students to start learning the procedure with the use of our model. After a certain time period of practice on our model, the test would have advanced to cadaver trials. The success rate of various components of the surgery such as needle placement and needle insertion distance would have been measured. These values would be compared side-by-side with success rates of students training on the gold standard model. A t-test would be performed to determine statistical significance between the two models. This would ensure validation of our design.

The construction of our model required certain levels of craftsmanship as well as the use of many different tools. This would be incredibly inefficient if the model were to be mass-produced. Had the group had more time and resources, we would have made a mold for the chest plate, ribs, and back plate of the model. This would allow for the entire synthetic bone structure to be injection molded with the use of any number of plastics rather than with the use of wood and PVC. This would decrease the overall cost of reproducing the model as well as increasing its sustainability as plastic is much more durable than wood.

A main goal of our model was to cut down on spending for replacement parts. This involved the use of inexpensive replacement parts that were durable and could withstand several surgeries without compromising the integrity of the model. The bladder we used to encase pleural fluid, successfully self-sealed when subjected to drainage with only a 16-gauge needle. However, during drainage with the use of a needle and catheter, the bladder continued to leak fluid after drainage. If the group had had a higher budget, we would have been able to obtain materials that are clinically proven to self-seal when punctured, such as the tubing used in the lumbar puncture model introduced to us at UMass Med. Although the bladder is inexpensive to replace, the model would be much more efficient if it were more resealable.

References

[1]Emergency Department Visits, *Center for Disease Control and Prevention*, 2012.

[2]Neily et al. Incorrect Surgical Procedures Within and Outside of the Operating Room. *Archives of Surgery*, 2009; 144 (11): 1028

[3]Emergency Care: Just 2%, *American College of Emergency Physicians,* 2009.

[4]Pailler-Mattei C., Zahouani H., *In Vivo* Measurements of the Elastic Mechanical Properties of Human Skin by Indentation Tests, *Medical Engineering and Physics,* 2008; 30: 599-606.

[5]Tobin J., Why Simulation Works, *Medicine of Michigan,* 2007; 9 (2): 1.

[6]Andre C., Velasquez M., Of Cures and Creatures Great and Small, *Issues in Ethics,* 1988; 1 (3).

[7]Gershman D., Group Takes Aim at University of Michigan's Use of Dogs to Train Doctors in Medical Procedures, *Ann-Arbor News,* 2009.

[8]Society Case Study, *Medical Simulation Corporation*, 2013.

[9]Carter Y.M., Marshall M.B., Open Lobectomy Simulator is an Effective Tool for Teaching Thoracic Surgical Skills. *Ann ThoracSurg,* 2009; 87 (5): 1546-50.

[10]Andreatta PB, Woodrum DT, Birkmeyer JD, Yellamanchilli RK, Doherty GM, Gauger PG, Minter RM. Laparoscopic skills are improved with LapMentor training: Results of a randomized, double-blinded study. *Ann Surg. 2006 Jun;243*(6):854-60; discussion 860-3

[11]Van De Graaff, Kent M. *Human Anatomy*.McGraw Hill Publishing, Burr Ridge, IL. 2002.

[12]Finley D.J., Rusch V.W., Anatomy of the Pleura, *ThoracSurgClin.*, 2011; 21 (2): 157-163.

[13]Sahn S. A., The Pathophysiology of Pleural Effusion, *Ann. Rev. Med.,* 1990; 41: 7-13.

[14]Thoracic Cavity, *Pearson Education Inc.,* 2004. <http://www.as.miami.edu/chemistry/2086/new-chap20/NEW-Chapter%2020_part1-CLASS_files/image003.jpg>

[15]Doelken P., How to Thoracentesis, *UptoDate Individual Web,* 2011.

[16]McGrath E. E., Anderson P. B., Diagnosis of Pleural Effusion: A Systematic Approach, *American Journal of Critical Care,* 2011; 20 (2): 119-128.

[17]Pleural Effusion Chest X-ray, *Cardiac Health,* 2010. <http://www.cardiachealth.org/sites/default/files/images/wordpress/uploads/2010/10/pleural-effusion-cxr.jpg>

[18]Boylan A, Broaddus VC. Tumors of the pleura. In: Mason RJ, Murray JF, Nadel JA, Broaddus VC, eds. *Murray and Nadel's Textbook of Respiratory Medicine*. 4th ed. Philadelphia, PA: Elsevier Health Sciences; 2005:1989–2010.

[19]How to Perform a Thoracentesis, *Tabers.com.* <http://www.tabers.com/tabersonline/ub?cmd=repview&type=tabers_21&name=e1250>

[20]Thoracentesis Figures: Outside and In, OncTalk, 2007. <http*://onctalk.com/wp-content/uploads/2007/03/thoracentesis-figures.jpg>*

[21]Sturm L, *et al.* Surgical simulation for training: Skills transfer to the operating room. *ASERNIP-S Report No. 61,* 2007.

[22]Cisler JJ and Martin JA. Logistical Considerations for Endoscopy Simulators.*Gastrointestinal Endoscopy Clinics of North America* 2006; 16(3): 565-575.

[23]Grober E.D., Hamstra S.J., Wanzel K.R., Reznick R.K., Matsumoto E.D., Sidhu R.S., Jarvi K.A. The educational impact of bench model fidelity on the acquisition of technical skill: the use of clinically relevant outcome measures. *Annals of Surgery* 2004; 240(2): 374-381.

[24]TraumaMan®, *Carolina's Simulation Center*.<http://www.carolinashealthcare.org/images/cmc/Carolinas%20Simulation%20Center/TraumaMan_small.jpg>

[25]TraumaMan® System, *SimuLab Corporation,* 2013. <http://www.simulab.com/product/surgery/open/traumaman-system>

[26]Torso Assembly, *SynDaver Labs™*.<http://syndaver.com/images/torso-assembly-02.jpg>

[27]Muscle Full Torso, *SynDaver Labs™*, 2012. <http://syndaver.com/product_info.php?products_id=431>

[28]Seymour NE and Rotnes JS. Challenges to the development of complex virtual reality surgical simulations. *Surgical Endoscopy* 2006; 20(11): 1774-1777.

[29]Virtual Reality Model, Web3d, 2012.
<http://www.web3d.org/files/images/pages/BestPaper-IEEEVR2012.jpg>

[30]Haque S and Srinivasan S.A meta-analysis of the training effectiveness of virtual reality surgical simulators. *IEEE Transactions on Information Technology in Biomedicine* 2006; **10**(1): 51-58.

[31]Medical Simulation Program, *Healthstream.* <http://blog.healthstream.com/Portals/62595/images/medical-simulation-program.jpg>

[32]Roberts KE, Bell RL, Duffy AJ.Evolution of surgical skills training. *World Journal of Gastroenterology* 2006; **12**(20): 3219-3224.

[33]Cronin D. S., Material Properties for Numerical Simulations for Human, Ballistic Soap and Gelatin, *Defense Research and Development Canada,* 2010: 1-21.

[34]Elastic Properties and Young Modulus for some Materials, *The Engineering ToolBox,* 2013.

[35] Schaefer R.J., Mechanical Properties of Rubber, *American Society for Testing and Materials,* 33.1-33.17.

[36] Juliano T.F. *et. al.*, Multiscale Mechanical Characterization of Biomimetic Physical Associated Gels, *Army Research Laboratory*, 2006;21 (8): 2084-2092.

[37] Williams J.M., Bartos III J.J., Wilkerson M.H., Elastic Modulus Dependence on Density for Polymeric Foams with Systematically Changing Microstructures, *Journal of Materials Sciences,* 1990; 24: 5134-5141.

[38] O'Callaghan P.T., Dynamics of Stab Wounds: Force Required for Penetration of Various Cadaveric Human Tissues, *Forensic Science International*, 1999; 104 (2-3): 173-178.

[39]Vu-Khanh T., Dolez P., Nguyen C.T., Gauvin C., Lara J., Needlestick Resistance of Protective Gloves, *IRSST*, 2012: 1-99.

[40]Composition of Rubber, Neoprene, *National Institute of Standards and Technology,* 2013.

[41]Material Properties, *Resoseal International*, 2008.

[42] Joint Industry Foam Standards and Guidelines, *Polyurethane Foam Association*, 1994.

[43] Shunji M., A Sensor to Measure Hardness of Human Tissue, *IEEE*, 2006: 388-391.

[44] Understanding and Applying Foam's Shore Durometer Hardness Values, *Foam Factory*, 2011.

[45] PVC Strength, *Plastic Materials Guidebook, PVC.org*, 2013.

[46] Materials, *Apex Medical Technologies Inc.*, 2010.

[47] Gallagher A.J., Dynamic Tensile Properties of Human Skin*, IRCOBI Conference*, 2012.

[48] Moy P., Weerasooriya T., Gunnarsson C.A., Tensile Deformation of Ballistic Gelatin as a Function of Loading Rate*, Army Research Laboratory,* 2008.

[49] Silicone Rubber, 1000 Psi (6.90 MPa) Tensile Strength, 45-55, *SAE International*, 2013.

[50] SynTissue Adult Skin*, SynDaver Labs™,* 2012.

[51] Shergold O.A., Fleck N.A., Experimental Investigation Into the Deep Penetration of Soft Solids by Sharp and Blunt Punches, With Application to the Piercing of Skin, *ASME Journal of Biomechanical Engineering*, 2005: 1-41.

[52] Suzuki T., Differences in penetration Force of Intravenous Catheters: Effect of Grinding Methods on Inner Needles of Intravenous Catheters, *Tokai J ExpClin Med.,* 2004; 29 (4): 175-181.

[53] Carvalho H., Rocha A. M., Monteiro J.L., Measurement and Analysis of Needle Penetration Forces in Industrial High-Speed Sewing Machine, *Journal of Textile Institute*, 2009; 100(4): 319-329.

[54] Gordon C. C., *et al.,*1988 Anthropometric Survey of U.S. Army Personnel: Methods and Summary Statistics. 1988.

[55] Stark P., Imaging of Pleural Effusions in Adults, *Wolters Kluwer Health*, 2012.

[56] Ganong W., "Fig. 34-7". *Review of Medical Physiology*; (21).

[57] Standardized Procedure for Thoracentesis, *UCSF Medical Center.*

Appendix

Appendix A: Glossary of Terms

Adipose tissue – specialized tissue in the body that stores fat

Anesthesia – local or general loss of pain; induced before a surgical procedure

Arrhythmia – irregular heartbeat

Axial – something that is placed along the line of an axis

Biopsy – removing cells or tissue from a body for diagnostic examination

CT scans – Computer Tomography; generate 3-D images of an object

Cadaver – dead human body used for medical training or research

Cardiovascular – relating to the heart and the circulatory system

Catheter – a tube inserted in a body to allow drainage of fluid

Chest tube insertion – using a tube to drain fluid from the lung cavity

Colonoscopy – examining the colon using an endoscope

Congestive heart failure - illness occurring from heart's inability to supply blood to the body

Diameter – straight line that passes through a center of the circle with endpoints on the circle

Diaphragm – muscle that extends across the bottom of the rib cage; separates thoracic cavity from abdominal cavity and aids in respiration

Discoloration – presence of color allowing the fluid to be seen

Dowels – solid, cylindrical rod made of wood in order to secure objects together

Durometer – hardness of a material

Dyspnea – inability to breathe

Esophagus – a muscular tube that allows the passage of food to the stomach

Force – a push or a pull made on an object

Hemostat – a clamp used to control bleeding during a surgical procedure

Laparoscopic– a surgery involving a thin, lighted tube inserted to obtain a biopsy

Lidocaine – local anesthetic used during surgery

Lobectomy – removal of a lung

Lobes – anatomical divisions of an organ

Longitudinally – parallel to a certain direction

MRI – Magnetic Resonance Imaging; used to visualize internal parts of the body

Malignant neoplasm – medical term for cancer

Mesothelial cells – membrane cells

Percussive dullness – noise made when tapping a patient over the fluid cavity

Pericardiocentesis – removal of fluid around the heart

Peritoneal fluid – fluid present in the abdominal cavity to lubricate surfaces

Pleural Space – space between the pleural layer of the lungs and the pleural layer of the ribs

Pleural effusion – excess presence of fluid in the pleural space

Posterolateral – back and away from the middle

Respiratory – relating to the lungs

Sepsis – infection in the bloodstream

Shear strength – ability of an object to resist a twisting motion

Sternum – bone plate on the front of the ribcage

Stopcock – a valve controlling the fluid of fluid from the container

Suture – stitches to close a wound post-surgery

T-test – statistical test used to determine the difference between two averages

Tensile modulus – ratio of stress over strain

Thermo-reversible – a temperature sensitive gel able to revert to original state

Thoracentesis – surgical procedure involving removal of fluid from the pleural space

Thoracic cavity – part of the body between the neck and the diaphragm

Trachea – windpipe; allows for transfer of air

Translucent – slightly penetrable by light

Transverse view – side to side

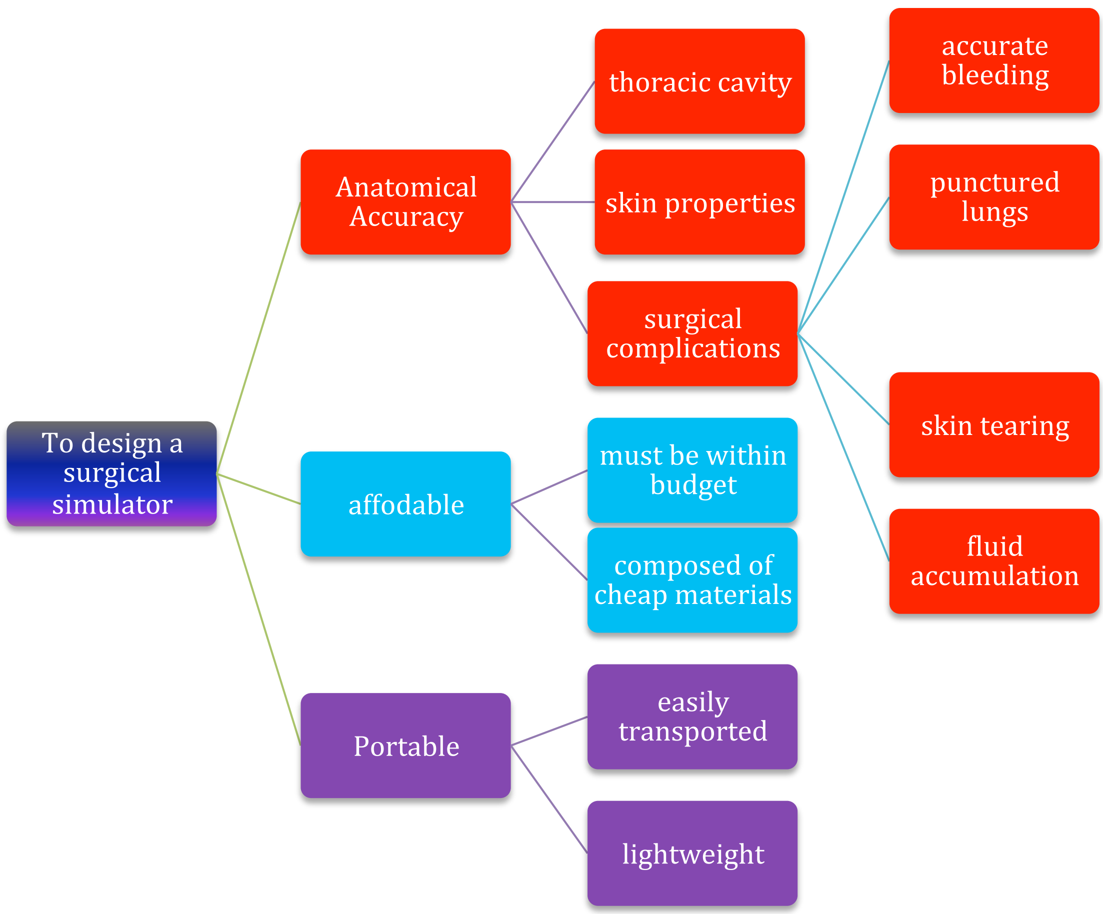
Ultrasound – procedure using sound waves for diagnostic purposes

Vena cava – large veins that return blood to the heart

Viscoelastic – a material that is both flowing/viscous and elastic

Viscosity – resistance to flow

Appendix B: Objectives Tree



Appendix C: Pairwise Comparison Chart

	Anatomical accuracy	Must be within budget	Composed of cheap materials	Easily transported	Lightweight	Total
Anatomical accuracy		1	1	1	1	4
Must be within budget	0		1	1	1	3
Composed of cheap materials	0	0		0	1	1
Easily transported	0	0	1		1	2
Lightweight	0	0	0	0		0

Appendix D: Thoracentesis Procedure Step by Step

Adapted from Standardized Procedure for Thoracentesis (UCSF Medical Center) [57]

STANDARDIZED PROCEDURE FOR
THORACENTESIS

I. **Definition**

A thoracentesis is a surgical puncture of the chest wall to aspirate fluid or air from the pleural cavity. A pleural effusion is an abnormal accumulation of fluid in the pleural space.

II. **Background Information**

A. Setting:

X Adults
X Both Inpatient & Outpatient clinical setting

B. Supervision: As delineated in the Standardized Practice Protocol for NP.

C. Indications: To determine the cause of pleural effusion and to remove pleural fluid therapeutically in the event of respiratory distress.

D. Precautions/Contraindications:
Thrombocytopenia, platelets < 20,000
Clotting abnormalities (Prothrombin time (PT), partial thromboplastin time prolongation >1.5 times normal), or anticoagulation therapy
Severe cough or hiccups (uncontrolled)

III. **Materials**

Sterile gloves,
Prepared thoracentesis tray or:
Stopcock
Blood transfer set
18-20 gauge 2" angiocatheter
4X4 gauze pads, 5 cc syringe with 25- 27 gauge
5/8" needle, & 22 gauge needle
1% lidocaine
Betadine
Hemostat
1 liter evacuated containers
(2) specimen containers
Sterile drapes

IV. **Thoracentesis Procedure**

A. Pre-treatment evaluation

1. Subjective:
   a. History of malignancy, pancytopenia, anticoagulant use, pleural effusion.
   b. Signs and symptoms: Small pleural effusions are usually asymptomatic. Large pleural effusions may cause dyspnea, pleuritic chest pain, and dry cough.
2. Objective:
   a. Patient evaluation: General appearance, vital signs, fever, pulse oximetry.
   b. Physical exam: Physical findings are general absent if less than 200-300ml of pleural fluid is present. Findings consistent with the presence of a larger pleural effusion include dullness to percussion, and the decreased whisper or breath sounds. In large pleural effusions that compress the lung, accentuation of breath sounds and egophony may be noted just above the effusion. A pleural friction rub indicates pleuritis. A massive pleural effusion may cause contra-lateral shift of the trachea and bulging of the intercostal spaces.
   c. Diagnostics: Chest x-ray; PA and lateral. Pleural fluid cause blunting of the costophrenic angles on chest x-ray. Blunting usually indicates that at least 300 ml of fluid is present. If <300 ml fluid is suspected or if the fluid appears to be loculated, a lateral decubitus film is helpful. Thoracentesis generally can be done safely if there is at least 10 mm fluid measurable on a decubitus chest x-ray.

      Flouroscopy or CT scan may be useful before thoracentesis if the fluid collection is < 10 mm thick or not freely moveable on the lateral decubitus x-ray view. Current CBC with platelets and differential, serum LDH, albumin, glucose, PT/PTT, chemistries as clinically indicated.

B. Patient Preparation

1. Explain the purpose, risks/benefits, and steps of the procedure.
   a. Risks:
      Pneumothorax, including tension pneumothorax
      Hemothorax, bleeding
      Hemorrhage
      Vasovagal episode
      Infection (empyema)
      Unilateral pulmonary edema
      Laceration of intra-abdominal viscera (puncture of liver or spleen).
      Subcutaneous emphysema
      Air embolism
      Pulmonary laceration

b. Benefits
- Yield information which may be lifesaving or significantly alter treatment
- Relief of respiratory distress.

2. Obtain consent from the patient or appropriate legal designee.
3. Check platelet count and/or presence of coagulopathy. Consult with Hematology/Oncology attending physician if platelet count is < 20,000, or there is known coagulopathy as to whether platelet transfusion or other intervention is needed prior to thoracentesis.
4. The patient does not need to restrict food or fluids.
5. Explain that he/she will receive a local anesthetic to minimize pain during the procedure.
6. Check patient history for hypersensitivity to the local anesthetic, and betadine.

C. Procedure performed

Procedure performed by a Nurse Practitioner who is currently licensed in the State of California, under the direct or indirect supervision of an attending physician, and who meets the clinical skills outlined below.

1. Position patient in the sitting position with arms and head resting supported on a bedside adjustable table. If unable to sit, the patient should lie at the edge of the bed on the affected side with the ipsilateral arm over the head and the midaxillary line accessible for the insertion of the needle. Elevating the head of the bed to 30 degrees may help.
2. The usual site for insertion of the thoracentesis needle is the posteriolateral aspect of the back over the diaphragm, but under the fluid level. Confirm site by counting the ribs based on chest x-ray and percussing out the fluid level. Mark the top of the dullness by washable ink mark or indenting the skin.
3. Select the thoracentesis site in an interspace below the point of dullness to percussion in the midposterior line (posterior insertion) or midaxillary line (lateral insertion).
4. Sterile technique should be used including gloves, betadine prep and drapes.
5. Anesthetize the skin over the insertion site with 1% lidocaine using the 5 cc syringe with 25 or 27-gauge needle. Next anesthetize the superior surface of the rib and the pleura. The needle is inserted over the top of rib (superior margin) to avoid the intercostals nerves and blood vessels that run on the underside of the rib (the intercostals nerve and the blood supply are located near the inferior margin). As the needle is inserted, aspirate back on the syringe to check for pleural fluid. Once fluid returns, note the depth of the needle and mark it with a hemostat. This gives an approximate depth for insertion of the angiocatheter or thoracentesis needle. Remove the anesthetizing needle.
6. Use a hemostat to measure the same depth on the thoracentesis needle or angiocath as the first needle. While exerting steady pressure on the patient’s back with the nondominant hand, use a hemostat to measure the 15- to 18- gauge thoracentesis needle to the same depth as the first needle. While exerting steady pressure on the patient’s back with the nondominant hand, insert the needle through the anesthetized area with the thoracentesis needle. Advance the needle until it encounters the superior aspect of the rib. Continue advancing the needle over the top of the rib and through the pleura, maintaining constant gentle suction on the syringe. Make sure you march over the top of the rib to avoid the neurovascular bundle that runs below the rib.
7. Attach the three way stopcock and tubing, and aspirate the amount needed. Turn the stopcock and evacuate the fluid through the tubing.
8. Remove the necessary amount of pleural fluid (usually 100 mL for diagnostic studies), but generally not remove more than 1500 mL of fluid at any one time because of increased risk of pleural edema or hypotension. A pneumothorax from needle laceration of the visceral pleura is more likely to occur if an effusion is completely drained.
9. When draining of fluid is completed, have the patient take a deep breath and hum, and gently remove the needle. This maneuver increases intrathoracic pressure and decreases the chance of pneumothorax. Cover the insertion site with a sterile occlusive dressing.

D. Post Procedure

1. Obtain an upright portable (expiratory) chest x-ray to evaluate the fluid level and to rule out pneumothorax.
2. For specimen handling, fill the tubes with the required amount of pleural fluid. Check that each tube is properly labeled by checking two patient identifiers- full name, date of birth and/or medical record number.
3. Pleural fluid should be sent for appropriate lab tests and may include pH, specific gravity, cell count and differential, protein, LDH, albumin, and glucose, culture and gram stain, acid-fast cultures and smears, fungal cultures and smears, viral culture. If a neoplasm is suspected, send for cytology (generally requires 1 L of fluid in a cytology bottle). Send for amylase if you suspect an effusion is secondary to pancreatitis, and Sudan stain and triglycerides if a chylothorax is suspected.
4. Document the procedure, patient's response, characteristics of fluid and amount, and patient response to follow-up.
5. Provide post-procedural analgesics as needed.

E. Follow-up

Instruct patient to call MD on-call or the clinic for any chest pain, increased cough, shortness of breath, or signs/symptoms of infection.

V. **Documentation**

Written record reflects: informed consent, patient response, side effects, amount of fluid withdrawn and lab tests sent.
All abnormal findings are reviewed with supervising physician.

VI. **Competency Assessment**

A. Initial Competence

Under the direct supervision of the attending physician, the Nurse Practitioner will perform the thoracentesis procedure successfully three times and will be evaluated for competence and technical skill. The Nurse Practitioner will demonstrate knowledge of the following:

1. Medical indications and contraindications of thoracentesis
2. Risks and benefits of the procedure.
3. Related anatomy and physiology
4. Consent process
5. Steps in performing the procedure
6. Documentation of the procedure
7. Ability to interpret results and implications in management.

B. Continued proficiency

1. A Nurse Practitioner who is currently licensed in the state of California and who meets the clinical skills as outlined above may perform the thoracentesis procedure. The Nurse Practitioner will demonstrate competence by successful completion of the initial orientation.
2. Each candidate will be initially proctored and signed off by an attending physician. The Nurse Practitioner must perform this procedure at least three times per year. In cases where this minimum is not met, the attending physician must again sign off the procedure for the Nurse Practitioner. The Nurse Practitioner will be signed off by the supervising physician after demonstrating 100% accuracy in completing the procedure.
3. Demonstration of continued competence shall be monitored through the annual evaluation and documentation of successfully performing of successful performing three procedures within the preceding year.

Appendix E: Thoracentesis Scope Analysis

Table 17: Final list of materials

Component	Material Used
Skin	Latex Layer (5/32 in.)
Muscle/Fat	EPDM Rubber
Ribs	PVC
Lungs	Speed Bag Bladder
Pleural Lining	IV bag
Fluid in Pleural Cavity	Colored Water

1. *Position patient in the sitting position with arms and head resting supported on a bedside adjustable table. If unable to sit, the patient should lie at the edge of the bed on the affected side with the ipsilateral arm over the head and the midaxillary line accessible for the insertion of the needle. Elevating the head of the bed to 30 degrees may help.*

   Overview: patient and all anatomical features

   Scope: Thorax

   Tests: Does model stand on own

   Can force be applied to the model?

   No leakage

2. *The usual site for insertion of the Thoracentesis needle is the posterolateral aspect of the back over the diaphragm, but under the fluid level. Confirm site by counting the ribs based on chest x-ray and percussing out the fluid level. Mark the top of the dullness by washable ink mark or indenting the skin.*

   Overview: Patient and all anatomical features and doctor

   Scope: Thorax and student training

   Tests: Does model make different sounds when tapping out?

3. *Select the Thoracentesis site in an interspace below the point of dullness to percussion in the midposterior line (posterior insertion) or midaxillary line (lateral insertion).*

   Overview: Patient and all anatomical features and doctor

   Scope: Skin, muscle/fat, rib (latex, EPDM, PVC)

   Tests: Can ribs be felt?

4. *Sterile technique should be used including gloves, betadine prep and drapes.*

   Overview: patient and all anatomical features, doctor, Thoracentesis tray

   Scope: thorax and student training

5. *Anesthetize the skin over the insertion site with 1% lidocaine using the 5 cc syringe with 25 or 27-gauge needle. Next anesthetize the superior surface of the rib and the pleura. The needle is inserted over the*

top of rib (superior margin) to avoid the intercostal nerves and blood vessels that run on the underside of the rib (the intercostal nerve and the blood supply are located near the inferior margin). As the needle is inserted, aspirate back on the syringe to check for pleural fluid. Once fluid returns, note the depth of the needle and mark it with a hemostat. This gives an approximate depth for insertion of the angiocatheter or Thoracentesis needle. Remove the anesthetizing needle

Overview: patient and all anatomical features, doctor, Thoracentesis tray

Scope: skin, muscle/fat, rib, pleura, fluid accumulation (latex, EPDM, PVC, shrink wrap, water)

Tests: Can needle pass through the material (latex, EPDM, shrink-wrap)?

Does water leak after puncturing shrink-wrap?

6. *Use a hemostat to measure the same depth on the Thoracentesis needle or angiocatheter as the first needle. While exerting steady pressure on the patient's back with the non-dominant hand, use a hemostat to measure the 15- to 18- gauge Thoracentesis needle to the same depth as the first needle. While exerting steady pressure on the patient's back with the non-dominant hand, insert the needle through the anesthetized area with the Thoracentesis needle. Advance the needle until it encounters the superior aspect of the rib. Continue advancing the needle over the top of the rib and through the pleura, maintaining constant gentle suction on the syringe. Make sure you march over the top of the rib to avoid the neurovascular bundle that runs below the rib.*

Overview: patient and all anatomical features, doctor, Thoracentesis tray

Scope: skin, muscle/fat, rib, pleura, fluid accumulation, lung, diaphragm (latex, EPDM, PVC, shrink wrap, water, rubber bladder, place holder)

Tests: Does needle leave giant hole in latex rubber

Does shrink-wrap make the desired "pop" due to lack of resistance?

Can model withstand pressure?

Are there signs if Needle punctured lung or diaphragm?

7. *Attach the three way stopcock and tubing, and aspirate the amount needed. Turn the stopcock and evacuate the fluid through the tubing.*

Overview: patient and all anatomical features, doctor, Thoracentesis tray

Scope: skin, muscle/fat, rib, pleura, fluid accumulation (latex, EPDM, PVC, shrink wrap, water)

Tests: Does water drain efficiently (no leakage)

Appendix F: Material Properties of Components of Thoracic Cavity

Component	Young's Modulus (GPa)	Ultimate Tensile Strength (MPa)	Poisson's Ratio
Ribs	13.5	124	0.2
Sternum	13.5	124	0.2
Lung	6.6×10^{-6}	-	0.45
Skin	$4.5\text{-}8.0 \times 10^{-5}$	-	0.8
Muscle	$3.2\text{-}9.6 \times 10^{-5}$	-	0.4

Appendix G: Feedback Required

Component	Type	Specification
Pleural Space	Proper fluid drainage	Color of fluid changed depending on the fluid drained
Incision	Location	3rd - 5th intercostal space
	Direction	See figure in Ch. 2
Ribs	Location	3rd – 5th intercostal space
	Translocation	Perpendicular to direction of ribs

Appendix H: Initial Fabrication Plans

Part	Material	Action	Tools	Notes
Ribs	6"D schedule 40 PVC tubing	Cut tubes to 2 cm thick rings	Drop Saw	
		Cut length to 7 1/2"	Band Saw	
		Drill holes to connect ribs to sternum and back plates	Drill Press	1/8" Twist drill bit
Sternum Plates	5/8"plywood	Trace exterior shape on surface	Pencil	
		cutexterior shape	Band Saw	
		cutexterior shape in half	Band Saw	
		Sand Edges	sand paper and sander	
		Notch out ends of wood to allow for rib connection	Jig saw	
		Drill holes for dowels	Drill Press	
Back Plates	5/8"plywood	Trace exterior shape on surface	Pencil	
		cutexterior shape	Band Saw	
		cutexterior shape in half	Band Saw	
		Sand Edges	sand paper and sander	
		Notch out ends of wood to allow for rib connection	Jig saw	
		Drill holes for dowels	Drill Press	
Skin	latex rubber	cut to size	Scissors	
		Tailor to fit model	Needle and thread	
Muscle/Fat layer	0.5"EPDM Rubber	Draw template on surface	Pencil	
		Cut according to template	Utility Knife	SIZE
		Cut template to length	Utility Knife	SIZE
Lungs	Speed bag bladder	Purchase		
Pleural Cavity/ Lining	IV bag	Purchase		

Appendix I: Manufacturing Process Step by Step

Sternum

A template of the left sternum was first drawn. It was designed to imitate the size and shape of the sternum and connective tissue of an average male (dimensions can be seen in FIGURE X). The template was then traced onto a piece of plywood 5/8" thick. Using a band saw, the sternum was cut out in two parts so that the model could be taken apart in case any pieces needed to be removed or fixed. The rough edges were all sanded until smooth. Notches were placed in the outer front edges of the design to allow for the connection of each rib. Using the drill press and a #38 twist drill bit, we drilled 2 holes on each of the edges to allow for the connection of the ribs. Holes were also drilled on the inside of each piece to allow for a dowel-connection system between the two halves of the sternum.

Vertebrae

A template of the backbone was created to replicate the size and shape of the backbone and connective tissue of an average male (dimensions can be seen in FIGURE X). The template was then traced onto a piece of plywood 5/8"thick. Using a band saw, the backbone was cut out in two pieces. The rough edges were all sanded until smooth. Notches were placed in the outer front edges of the design to allow for the connection of each rib. Using the drill press and a #38 twist drill bit, we drilled 2 holes on each of the edges to allow for the connection of the ribs. Holes were also drilled on the inside of each piece to allow for a dowel-connection system between the two halves of the sternum.

Ribs

Each rib was cut out of a tube of PVC pipe with an outer diameter of 6 inches. A drop saw was used to cut the tube into rings of 2 cm thickness. A band saw was used to remove part of each ring until the length of each ring was 7 ½". Using a drill press and a 1/8" twist bit, we then made two holes on each end of every rib. These holes were used to screw the ribs to the connectors of both the sternum and back plates.

Sternum, Vertebrae and Rib Assembly

Each half of both the sternum and vertebrae were connected to each other by dowels. A dowel of 1/8" diameter was cut into 3 1"pieces. These pieces were glued into the precut holes one side of both the sternum and back plate. The other half of the sternum and back plate were connected respectively. Each rib was then screwed in to its corresponding place on both the sternum and back plate.

Muscle and Fat layer Design and Fabrication

EPDM Rubber with a thickness of 0.5 inches was intended to be used for the design of the muscle and fat layer. However, we received material with a thickness of 1". Because the wrong thickness was purchased, we had to create a frame for the material to cut the thickness in half. The frame was created using scraps of plywood. The base of the frame was 22 1/2 "by 14 ½". 2 rods of ½"plywood were cut to 22 ½"and screwed to their respective sides of the base. 2 rods of ½"plywood were cut to 14 ½"and screwed to their respective sides of the base. A rectangular piece of EPDM 22 1/2"x 14/1/2"was cut out of a sheet of EPDM rubber using a utility knife. This sheet of rubber was then placed securely into the frame previously created. A rope saw was then used to slice the thickness of the EPDM rubber in half.

7 slices were then cut into each end of the rubber to allow for a tight fit around the ribcage. Each flap was tightly wrapped around the base of the model. Once the two flaps met each other in the front, the excess material was removed. This was performed for both sides of each rib.

Muscle and Fat layer Assembly

The muscle and fat layer were attached to the ribs, sternum and back plate via Velcro®.

Skin Design and Fabrication

A 22 ½"by 14 ½" sheet of latex rubber was wrapped around the model. Markings were made on the center of each side of the model. Incisions were then made 7"on each side to be taken in. This was hand sewed using needle and thread.

Skin Assembly

The skin was made to fit around the model with a slight overlap so that it could be attached with Velcro® on for easy removal.

Lungs Design and Fabrication

Because the lungs were needed as place holders, speed bag bladders were purchased. The speed bag bladders are placed inside of the model and filled to their maximum capacity to secure a tight fit.

Pleural Cavity Design and Fabrication

A CamelBak® bag was purchased for the pleural cavity and lining. It is attached to back wall of the sternum using 3 binder clips.

Mass Production and Assembly Plan

The entire ribcage including the ribs, sternum and back plate would be pre-assembled with the muscle/fat layer and skin pre attached. The lungs and pleural cavity/lining would be included; however, these items will be left for the user to assemble.

The individual ribs would be made by injection molding PVC, into appropriate molds. This would allow us to make the simulator much more anatomically correct.

The muscle/fat layer would be cut with a laser to saw out of an EPDM sheet of the correct thickness.

Appendix J: Validation of Must Have User Requirements

	User Requirements	Target Value	Actual Value
Inspection	Include key thoracic cavity components: Ribcage, Pleura, Lungs, Skin, Muscle/Fat	Yes	Yes
Inspection	Have Skin That Allows Thoracic Cavity Access	Yes	Yes
Inspection	Have Penetrable Pleura	Yes	Yes
Subjective Testing **Strain Gauge**	Respond Correctly	Likert Scale Value ≥ 3 Rib Spread Force ≈ 100 N	- Rib Spread Force ≈ 95 N
Inspection	Have Resealable Skin	No visible punctures	No visible punctures
Inspection	Have Penetrable Skin	Yes	Yes

Appendix K: Instructions for Use

Components:

1. Left Sternum Plate
2. Right Sternum Plate
3. Left Back Plate
4. Right Back Plate
5. Ribs (x 14)
6. Muscle Layer
7. Skin
8. Pleural Cavity
9. Clips (x2)
10. Lungs (x2)
11. Stopcocks (x2)

The ribcage will come preassembled as follows:

- Left sternum and right sternum plate will be connected via dowels
- Left back plate and right back plate will be connected via dowels
- Ribs will connect the plates together via screws
- The muscle layer will be attached via Velcro®
- The skin layer will be attached via Velcro®

Assembly of parts:

- Fill Pleural cavity with water to indicated line
- Attach Pleural cavity to its specific location (As marked on the model) via the clips
- Insert lungs into model
- Inflate lungs with air pump
- Place stopcocks in air passage of lungs to allow for easy deflation

Use:

- Once all components are in place, a Thoracentesis tray is needed
- Perform Surgery as normal

Replacement of Parts:

- If punctured, lungs can be removed and replaced for a small fee
- If reseal ability of Pleural Cavity disappears, it can be removed and replaced for a small fee
- The skin layer can be removed from the Velcro® and replaced for a small fee
- The muscle layer can be removed from the Velcro® and replaced for a small fee

Appendix L: Expenses Report

Component	Item	Quantity	Cost/Quantity	Gross Cost
Plates	Plywood	1	$8.97	$8.97
Ribs	6" x 10’ PVC Pipe	1	$26.33	$26.33
	Screws	56	$0.031	$1.74
Connectors	Dowel	1	$1.68	$1.68
Lungs	Speed Bag Bladder	2	$3.99	$7.98
	Stopcocks	2	$0.75	$1.50
Pleura	CamelBak® Bag	1	$13.00	$13.00
	Rubber Cement	1	$3.14	$3.14
Muscle	EPDM (22 x 14 x .5)	1	$7.70	$ 7.70
	3/4" Stick Velcro® Roll	3	$4.35	$13.05
Skin	Latex Rubber (22 x 14 x .02)	1	$7.70	$7.70
Total Cost				$92.79

Appendix M: Additional Images of the Model

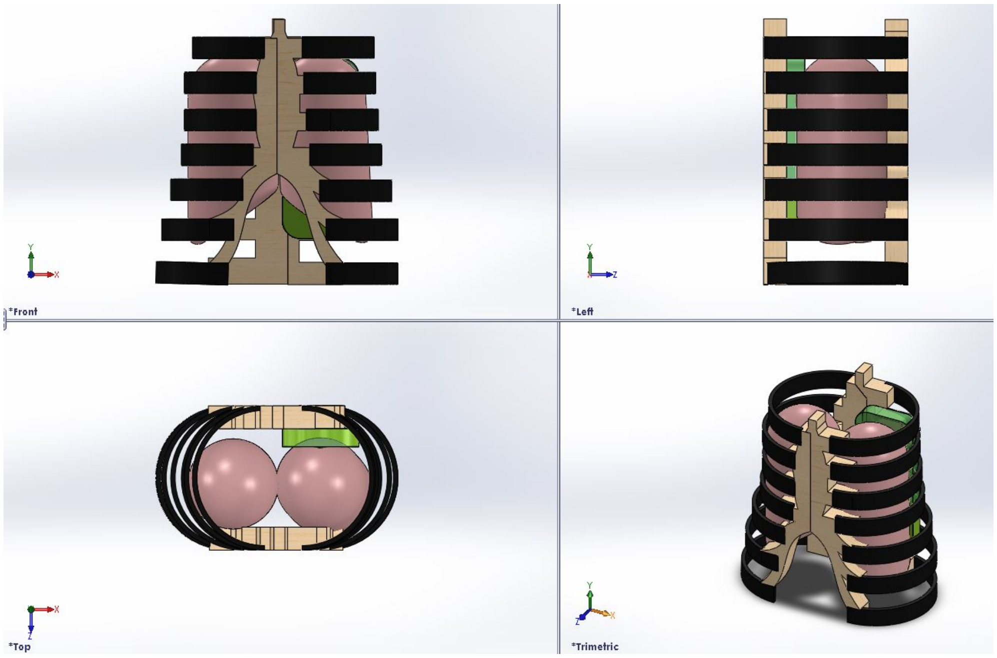


Figure 31: CAD model of ribcage assembly in 4 views

Figure 32: Thoracentesis kit

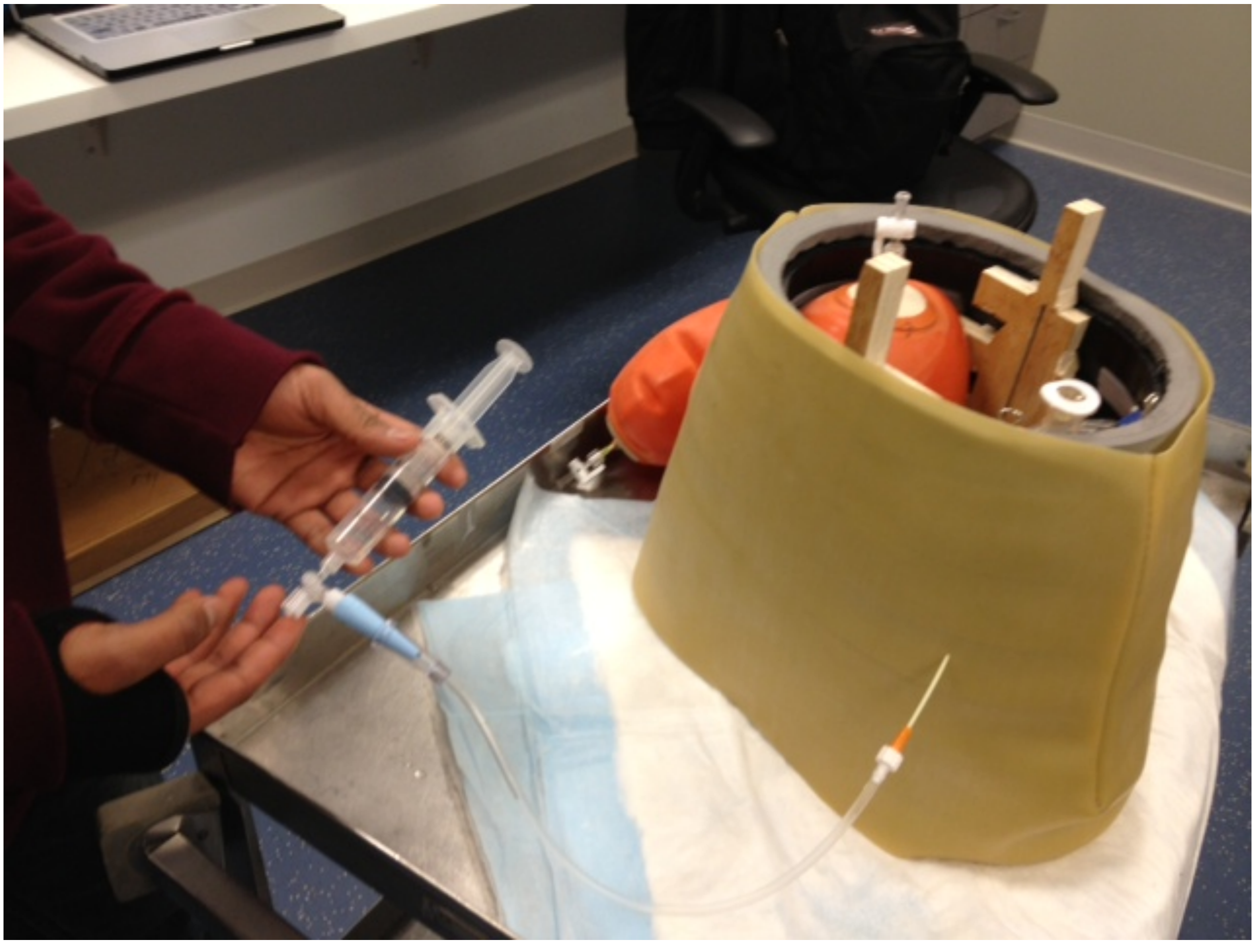
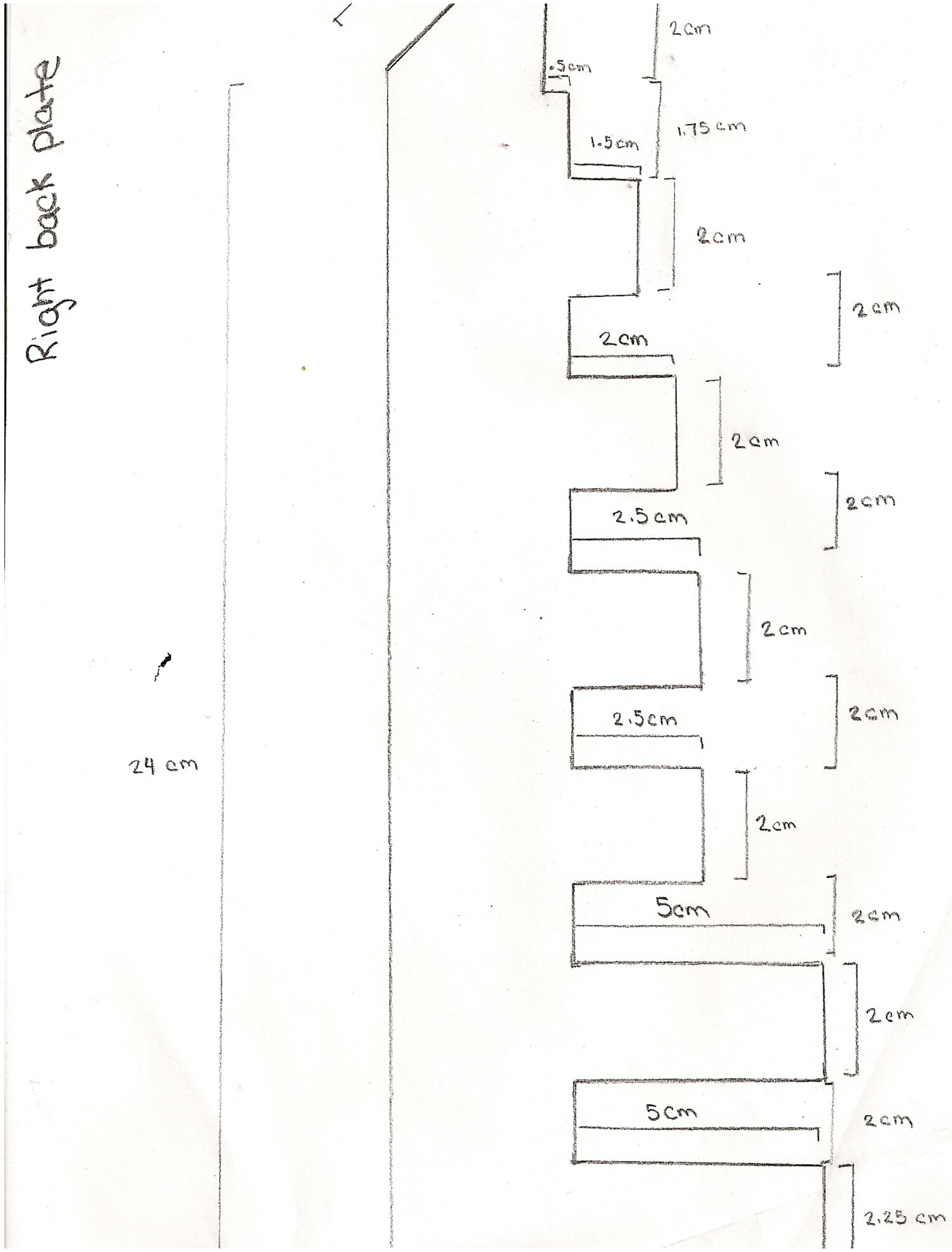
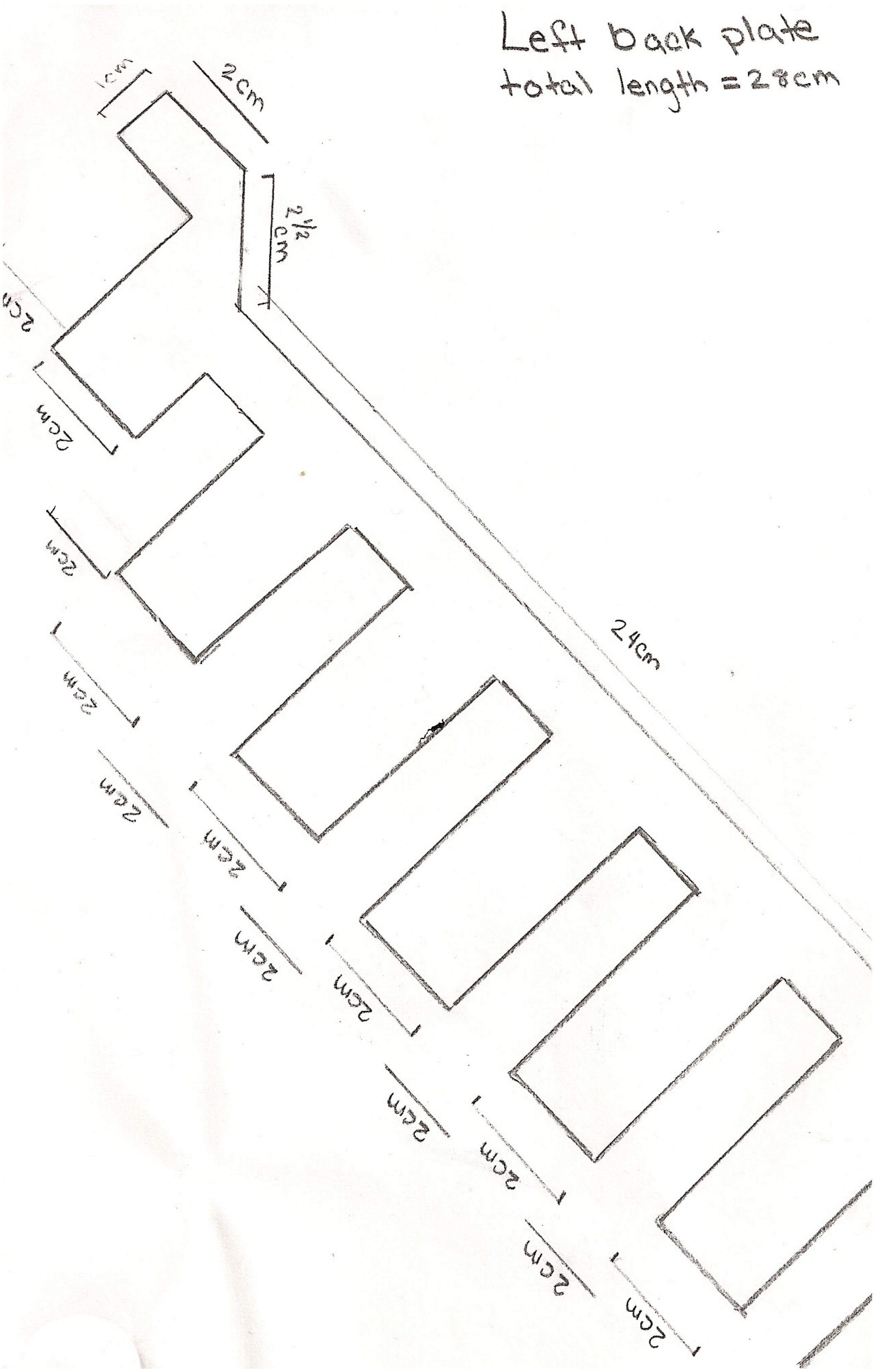
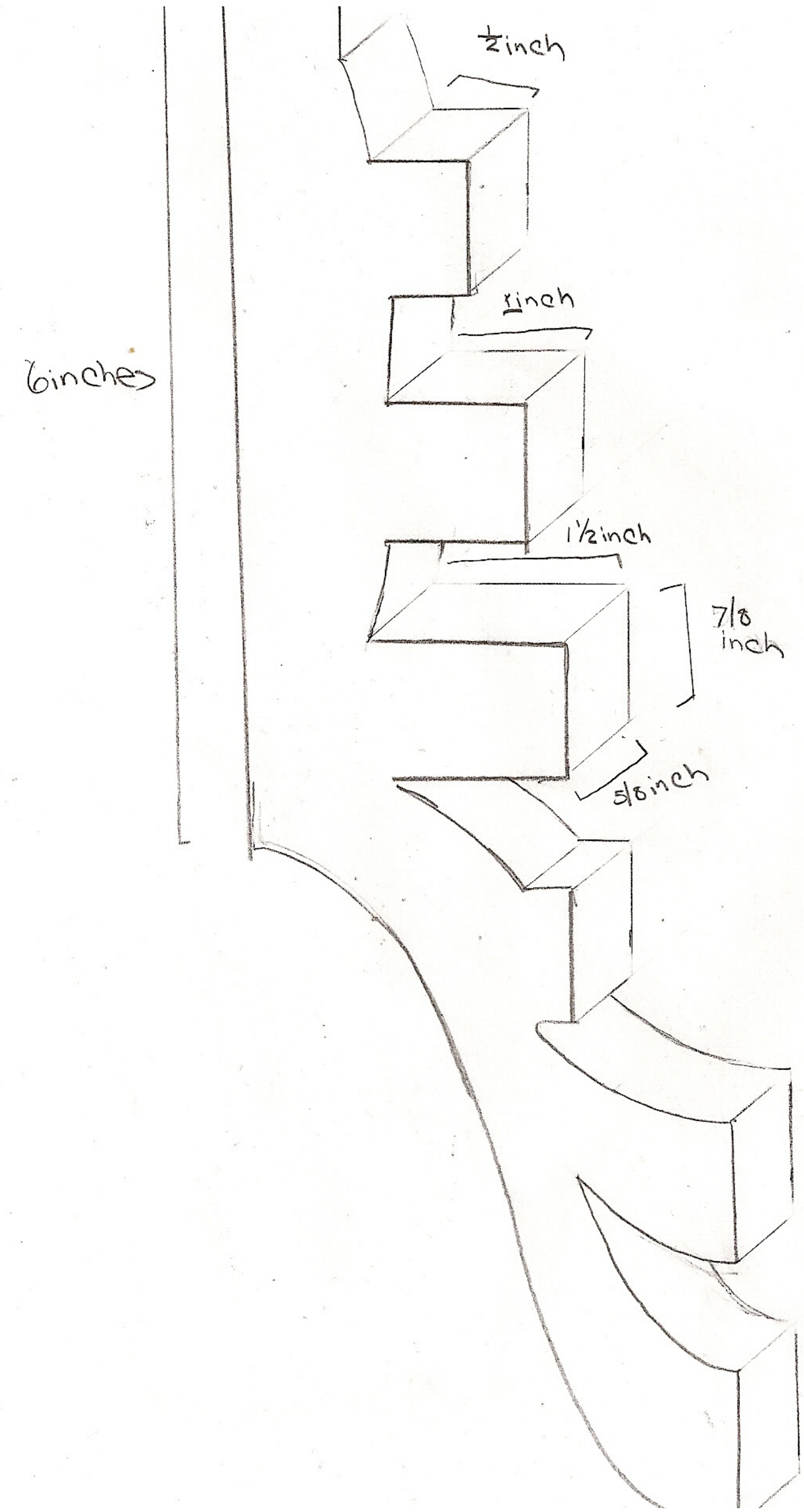


Figure 33: Thoracentesis setup with catheter tubing

Appendix N: Dimensional Sketches for Design Components




Left back plate
total length = 28cm
1cm
2cm
2½ cm
2cm
2cm
2cm
24cm
2cm
2cm
2cm
2cm
2cm
2cm
2cm
2cm
2cm



½ inch
1 inch
6 inches
1½ inch
7/8 inch
5/8 inch

Appendix O: Evaluation Forms

Surgical Simulator Evaluation Form

Name: Melinda Taylor

Occupation: Sr. Engineer

Date: 4-2-13

Please rate the following items within the scale indicated:

	1 Poor	2	3 Fair	4	5 Excellent
The model accurately represents the human thorax				X	
Effectiveness of model as a surgical training device					X
Accuracy of tissue layers in simulating feeling for the ribs					X
Accuracy of the model in simulating needle penetration feel					X
Accuracy of physical landmarks to aid in the procedure					X
Fluid drainage rate					X
Compatibility of model with surgical instruments (catheter, different gauge needles)					X
Resealability				X	
Repeatability of procedure					X
Durability				X	
Manufacturability					X
Cost of model					X
Aesthetics				X	
Would you recommend using this product?					X

How well does the model represent the human thorax?

The model does a great job of simulating the shape, size and anatomical characteristics.

What are the main advantages of using this model as a teaching tool for Thoracentesis?

Thoracentises models on the market can be expensive, difficult to maintain/repair and travel with. This model is highly portable, easy to use and maintain.

What are the disadvantages?

None that I identify.

Are there any future recommendations towards the improvement of the model?

Some cosmetic enhancement to finish would be nice but does not effect performance.

Using rubber cement or other coating on inner fluid bag will increase Longevity of model.

Additional comments (if any):

The Dean of the Medical School would like to start training medical students and residents using this model.

Surgical Simulator Evaluation Form

Name: Deb Heitmann

Occupation: MD Emergency Medicine

Date: 4/2/13

Please rate the following items within the scale indicated:

	1 Poor	2	3 Fair	4	5 Excellent
The model accurately represents the human thorax			X		
Effectiveness of model as a surgical training device				X	
Accuracy of tissue layers in simulating feeling for the ribs				X	
Accuracy of the model in simulating needle penetration feel				X	
Accuracy of physical landmarks to aid in the procedure				X	
Fluid drainage rate					X
Compatibility of model with surgical instruments (catheter, different gauge needles)				X	
Resealability			X		
Repeatability of procedure				X	
Durability				X	
Manufacturability					
Cost of model					
Aesthetics			X		
Would you recommend using this product?				Yes	

How well does the model represent the human thorax?

For the purposes of finding landmarks ~~of~~ on thorax to perform thoracocentesis, it is very effective

With more refinement, resources and time, the model could allow more realism eg. injection of local anesthetic; tapping out of fluid level

What are the main advantages of using this model as a teaching tool for Thoracentesis?

Simple
Transportable/Mobile
Easy maintenance
Accurate to mimic ribs/location of needle and
accomodate needle/drainage setup

What are the disadvantages?

- limited realism of model ie shoulder blades/head
- current skin does not accomodate local infiltration with anesthetic.
- bladder resilience and guaranteed ~~pos~~ correct positioning

Are there any future recommendations towards the improvement of the model?

- Bladder landmarks inside thorax to guarantee proper position.
- Absorbent skin to accomodate lidocaine
-

Additional comments (if any):

Great project